Table 4: Clinical evidence tables for uterine closure techniques

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Brocklehurst,P., Caesarean section surgical techniques: A randomised factorial trial (CAESAR), BJOG: An International Journal of Obstetrics and Gynaecology, 117, 1366-1376, 2010 **Ref Id** 109401 **Country/ies where the study was carried out** UK and Italy **Study type** RCT (2x2x2 factorial) **Aim of the study** Determine whether any of the following alternative surgical	**Sample size** n=3033 1483 single layer closure; 1496 double layer closure **Characteristics** mean age: 30.6 SD 5.9 years mean GA at study entry: 39.0 SD 2.0 weeks **Inclusion criteria** Women undergoing delivery by their first caesarean section, this was planned to be performed through the lower uterine segment and there was no clear indication for any particular technique to be used.	**Interventions** Single versus double layer uterine closure. Single layer closure involves bringing both edges of the uterine incision together with a single layer of sutures. In double-layer closure, the uterine incision is closed with two layers of sutures. The first layer opposes the endometrial aspect of the uterine muscle layer and the second brings together the serosal layer.	**Details** Antibiotics as standard: not reported Type of incision used: Pfannenstiel or Joel-Cohen, surgeon's discretion, asked to remain consistent Uterine closure: single or double layer Exteriorisation of uterus: not reported Suture material: no restrictions on the type of suture material that could be used, but should remain consistent (vicryl/ dexon/ other) Type of suture/stitch pattern: not reported Peritoneal closure: Half closure, half non-closure Skin closure: same whether single or double layer (subcuticular/ staples/ clips/ interrupted/ other) Statistics used: Patients were analysed in the groups to which they were	**Results** single layer: allocated n=1505; received allocated: 1377; analysed 1483; excluded 22 double layer: allocated 1506; received allocated 1477; analysed 1496; excluded 10 <u>Antibiotics for febrile morbidity</u> single: n=12/1483; RR=1.09 (0.38-3.19) double: n=11/1496 <u>Antibiotics for wound infection</u> single: n=188/1483; RR=1.01 (0.79-1.29) double: n=188/1496 <u>Blood transfusion</u> single: n=54/1483; RR=0.93 (0.57-1.49) double: n=59/1496	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *telephone randomisation service was employed to allocate the interventions using a minimisation algorithm to ensure comparability between women (**LOW**)* • **Allocation concealment** *Allocation was made available to the operating surgeon prior to the onset of surgery (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *no information (**UNCLEAR**)* • **Blinding of personnel:** *Allocation was made available to the operating surgeon prior to the onset of surgery (**HIGH**)*

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techniques affect the risk of adverse outcomes: single- versus double-layer closure of the uterine incision; closure versus nonclosure of the pelvic peritoneum; liberal versus restricted use of a subrectus sheath drain? **Study dates** November 2000 - June 2006 **Source of funding** The trial was funded by the NHS South East Region Research and Development Office. The funding source had no role in the study design, the collection and interpretation of the data, writing of the report or decision to submit the paper for publication.	**Exclusion criteria** Women under 16years old		assigned, regardless of deviation from the protocol or treatment received. Comparative statistical analysis entailed the calculation of the relative risk (RR) plus the 95% confidence interval (95% CI) for the primary outcome and 99% CI for the secondary outcomes to take account of multiple comparisons. Pairwise interactions between the different interventions were examined		**Detection bias - Blinding of outcome assessment:** *information from medical records/patient notes (**LOW**)* **Attrition bias - Incomplete outcome data:** *Analysis by intention-to-treat. Exclusions due to vaginal delivery (not CS), withdrawal of consent, clinical reason at time of surgery, error, or lost to follow up - single layer 1.5%, double layer 0.7% (**LOW**)* **Reporting bias - Selective reporting:** *Appears to report as per protocol (**LOW**)* **Other information**
Full citation Chapman, S. J., Owen, J., Hauth, J. C., One- versus two-layer	**Sample size** n=164 from original 906 women (Hauth 1992); n=83/164 had	**Interventions** One layer or two layer closure of uterine incision in previous pregnancy	**Details** As described by Hauth 1992 - low transverse uterine incision; 1-0 chromic catgut sutures	**Results** n=70/145 single layer; n=75/145 double layer used in final analysis Vaginal delivery	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW (as in Hauth 1992)**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
closure of a low transverse cesarean: The next pregnancy, Obstetrics and Gynecology, 89, 16-8, 1997 **Ref Id** 652438 **Country/ies where the study was carried out** USA **Study type** Retrospective (medical record search) Follow up to RCT (Hauth 1992) **Aim of the study** determine whether a low transverse cesarean closure method in one or two layers affects subsequent pregnancy outcome. **Study dates** Follow up to Hauth 1992 in subsequent 4 years	single layer; n=81/163 had two layer n=19/164 had elective c-section without labour, and were excluded from analysis n=70/145 single layer; n=75/145 double layer used in final analysis **Characteristics** Not reported - full cohort data in Hauth 1992 **Inclusion criteria** Women with subsequent pregnancy in 4 years after Hauth 1992 study Gestation longer than 18 weeks Delivered at study institution **Exclusion criteria** Twin gestations (violates the assumption of independence) excluded from neonatal analyses		Statistics used: Statistical analyses were conducted with the Statistical Analysis System (SAS Institute, Inc., Cary, NC) version 6.04. Chi-square, Fisher exact test, the Student t-test, and Wilcoxon rank-sum test were used for comparisons where appropriate. Continuous data are presented as mean +/-1 standard deviation (SD). P </=0.05 represented statistical significance.	single: 56% (n=39/70); double: 64% (n=48/75) <u>Uterine dehiscence</u> single: n=1/70; double: n=0/75	• **Random sequence generation** *computer generated randomisation (**LOW**)* • **Allocation concealment** *Envelopes were opened before initiation of c-section to preclude selection/operator bias (**LOW**)* **Performance bias: LOW** • **Blinding of participants:** Outcomes from medical records - no effect from prior knowledge of study allocation *(**LOW**)* • **Blinding of personnel:** Outcomes from medical records - no effect from prior knowledge of study allocation *(**LOW**)* **Detection bias - Blinding of outcome assessment:** *Outcomes from medical records - no effect from prior knowledge of study allocation (**LOW**)* **Attrition bias - Incomplete outcome data (for each outcome):** Large number of women excluded from analysis (n=19/164; 12%) *(**HIGH**)* **Reporting bias - Selective reporting:** *No access to protocol for long term outcomes (**UNCLEAR**)* **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported					
Full citation Chitra, K. L. S., Nirmala, A. P., Gayetri, R., Jayanthi, N. V., Shanthi, J. S., Misgav Ladach cesarean section vs Pfannenstiel cesarean section, Journal of obstetrics and gynaecology of India, 54, 473-477, 2004 **Ref Id** 930777 **Country/ies where the study was carried out** India **Study type** RCT **Aim of the study** assess the efficacy, safety, duration, blood loss, need for suture material and post-operative stay, and compare it to Pfannenstiel caesarean section in	**Sample size** n=200: 100 randomly allocated per group **Characteristics** mean age: (Group1) 24.93 years; (Group2) 24.98 years mean GA: (1) 39.15 weeks; (2) 38.84 weeks mean birthweight: (1) 3020g; (2) 3039g **Inclusion criteria** all women posted for elective or emergency primary caesarean section **Exclusion criteria** • women with previous c-section • obstructed labour • previous abdominal surgery • twin pregnancy • placenta praevia • abruptio placenta	**Interventions** **Group 1: Pfannenstiel:** incision: pfannenstiel; closure: double layer **Group 2: Misgav-Ladach**: incision: Joel-Cohen; closure: single layer continuous locking	**Details** Antibiotics as standard: elective c-sections: 1g cephalexin 6 hourly for 3 doses; emergency cases cephalexin 500mg 6 hourly for 5days Type of incision used: (1) pfannenstiel; (2) joel-cohen Uterine closure: (1) two-layers; (2) one-layer Exteriorisation of uterus: not reported Suture material: uterine: chromic catgut; skin closure: black silk; rectus sheath closure: proline no1 Type of suture/stitch pattern: single: continuous locking pattern; double "2 layer" Peritoneal closure: not reported Skin closure: with black silk; (1) 7-8 stitches; (2) 3 stitches Other: all c-sections performed under spinal or general anaesthetic. Surgery allocation by random numbers drawn by the floor nurse. floor nurse, surgeon, and scrub nurse	**Results** Blood transfusion Group 1 (double): n=2/100; Group 2 (single): n=1/100	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *Random allocation using random numbers drawn by floor nurse (**LOW**)* • **Allocation concealment** *Staff aware of allocation (**HIGH**)* **Performance bias: HIGH** • **Blinding of participants:** *Women under anaesthesia (**UNCLEAR**)* • **Blinding of personnel:** *Surgeon and surgical staff aware of allocation* - unable to blind staff to allocation *(**HIGH**)* **Detection bias - Blinding of outcome assessment:** *Surgical staff collected outcomes - floor nurse measured operation time, blood loss estimated by surgeon and nurses from suction bottle, gauzes and pack used, scrub nurse counted number of sutures used (**HIGH**)* **Attrition bias - Incomplete outcome data (for each outcome):** No detail regarding exclusions *(**UNCLEAR**)*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
women undergoing c-section **Study dates** Not reported **Source of funding** Not reported	• ruptured uterus		recorded outcome measures		**Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation CORONIS Collaborative Group., Caesarean section surgical techniques (CORONIS): a fractional, factorial, unmasked, randomised controlled trial, Lancet (London, England), 382, 234-48, 2013 **Ref Id** 930877 **Country/ies where the study was carried out** UK (Argentina, Chile, Ghana, India, Kenya, Pakistan, Sudan) **Study type** RCT 2x2x2x2x2	**Sample size** total enrolled in study n=15,935 n=9416 allocated to closure of uterus; single: n=4705; double: n=4711 received allocated treatment: single: n=3913 (83%); double: n=4603 (98%) final analysis: single: n=4639 (99%); double: n=4647 (99%) **Characteristics** Maternal age: single: 26.9±5.4 years; double: 26.8±5.4 years Nulliparous: single: n=2160/4639 (47%); double: n=2248/4647 (48%) No previous c-section: single: n=3182/4639	**Interventions** **Blunt v sharp entry:** For sharp entry, the abdomen was entered using a scalpel to divide the abdominal skin. Each subsequent layer of the abdomen was then separately identified and divided using either a scalpel or scissors. In blunt entry, the abdomen was entered using a scalpel to divide the abdominal skin. The scalpel was then used to divide the fat and rectus sheath in the midline and the rectus sheath incision extended manually. The parietal peritoneum was then entered digitally and the defect enlarged manually. **Exteriorisation of the uterus** for repair versus intraabdominal repair: once the placenta had been delivered, either the uterus was drawn from the pelvis to rest on the anterior abdominal wall so that the uterine incision could clearly be visualised or the	**Details** Suture pattern: could be a continuous, continuous locking, or an interrupted layer of sutures. For sites where chromic catgut versus polyglactin-910 was one of the assigned intervention pairs, surgeons were asked to restrict their use of the allocated suture material to repair of the uterine incision and to use their usual suture material for all other layers. All non-allocated surgical elements and all other aspects of the caesarean section procedure were undertaken at the discretion of the surgeon. In particular, there were no restrictions on the type of suture material that could be used, and standard measures to achieve haemostasis were	**Results** antibiotics for febrile morbidity single: n=47/4639; double: n=47/4647; RR=1.0 (95%CI 0.59-1.70) antibiotics for wound infection single: n=353/4639; double: n=379/4647; RR=0.93 (0.78-1.12) antibiotics for endometritis single: n=38/4639; double: n=34/4647; RR=1.12 (0.61-2.05) further operative procedures single: n=74/4639; double: n=87/4647; RR=0.85 (0.57-1.28) further operative procedures on wound single: n=30/4639; double: n=38/4647; RR=0.79 (0.42-1.48) blood transfusion	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *Randomisation was done using a bespoke secure web-based system, with a 24-h automated telephone back-up. The system allocated a number corresponding to a unique allocation envelope held at participating sites. The allocation numbers were generated by computer implementation of a pseudo-random generating algorithm. Each envelope contained an allocation sheet detailing the three allocated interventions for a woman, as a reminder to the surgeon. In instances where there was no internet or telephone connectivity, the recruiting clinician selected the lowest sequentially numbered allocation envelope. (**LOW**)*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study examined five elements of the caesarean section technique in intervention pairs: • blunt versus sharp abdominal entry; • exteriorisation of the uterus for repair versus intraabdominal repair; • single-layer versus double-layer closure of the uterus; • closure versus non-closure of the peritoneum (pelvic and parietal); • chromic catgut versus polyglactin-910 for uterine repair **Study dates** 20 May 2007 - 31 Dec 2010 **Source of funding**	(69%); double: n=3183/4647 (69%) One previous c-section: single: 1457 (31%); double: 1464 (31%) **Inclusion criteria** women who were to undergo birth by lower segment caesarean section through a transverse abdominal incision, irrespective of fever in labour, gestational age, or multiple pregnancies **Exclusion criteria** • clear indication for a particular surgical technique or material to be used that prevented any of the allocated interventions being used, • if they had more than one previous caesarean section, • if they had already been recruited into the trial	uterus was repaired while in the pelvis. **Single-layer v double-layer** closure of the uterus: the uterine incision was closed with either one or two layers of sutures. Each layer could be closed using any accepted technique. Haemostasis of the incision could be done with additional sutures as judged necessary by the surgeon regardless of the method of closure undertaken. **Peritoneum closure v non-closure:** the pelvic and parietal peritoneum was either closed or not closed. For either technique, haemostasis was achieved as usual, including, where necessary, the use of haemostatic sutures. **Suture material:** chromic catgut versus polyglactin-910 for uterine repair, the uterus was repaired using either number 1 chromic catgut (Medsurge, Philadelphia, PA, USA) or number 1 polyglactin-910 (Ethicon, Livingston,NJ, UK).	employed regardless of the allocated intervention. A sample size of 15,000 women was needed, with at least 9000 women in each intervention pair, to have at least 80% power to detect a 15% relative risk reduction in the primary outcome from a baseline incidence of 15%, assuming 15% loss to follow-up.	single: n=76/4639; double: n=79/4647; RR=0.96 (0.64-1.45)	• **Allocation concealment** *All randomisation data were held centrally at the international coordinating centre (National Perinatal Epidemiology Unit Clinical Trials Unit) (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *All investigators, surgeons, and participants were unmasked to treatment allocation (**HIGH**)* • **Blinding of personnel:** *All investigators, surgeons, and participants were unmasked to treatment allocation. (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *All investigators, surgeons, and participants were unmasked to treatment allocation. (**HIGH**)* **Attrition bias - Incomplete outcome data (for each outcome):** *Analysis by intention-to-treat. n=206/15935 (1.3%) women were excluded from the analysis, of whom 143 (0.9%) had a vaginal birth. Women were evenly distributed among the intervention pairs and were excluded from the analysis because they were not at risk of wound-related problems (**LOW**)* **Reporting bias - Selective reporting:** *As described in the protocol (**LOW**)*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
UK Medical Research Council and WHO					**Other information**
Full citation CORONIS collaborative group., Caesarean section surgical techniques: 3 year follow-up of the CORONIS fractional, factorial, unmasked, randomised controlled trial, Lancet (London, England), 388, 62-72, 2016 **Ref Id** 930878 **Country/ies where the study was carried out** UK (Argentina, Chile, Ghana, India, Kenya, Pakistan, and Sudan) **Study type** RCT follow up **Aim of the study** 3 year follow up of CORONIS study 2013 **Study dates**	**Sample size** Women with subsequent pregnancy (as proportion of number assessed in original study) single: n=1889/3709 (51%); double: n=1904/3702 (51%) women with subsequent viable pregnancy single: n=1611/3709; double n=1624/3702 **Characteristics** Maternal deaths post-CORONIS 2013 single: n=25/4613; double: n=32/4621; RR=0.78 (0.46-1.32) Babies from subsequent viable pregnancy single: n=1630; double: n=1646 Stillbirth in subsequent viable pregnancy single: n=34/1630; double: n=28/1646; RR=1.23 (0.75-2.01) Neonatal death in subsequent viable pregnancy	**Interventions** As in CORONIS 2013	**Details** As in CORONIS 2013	**Results** c-section in subsequent pregnancy single: n=1312/1630 (81%); double: n=1353/1646 (82%); RR=0.98 (0.95-1.01) uterine rupture in subsequent pregnancy single: n=1/1610 (<1%); double: n=2/1624 (<1%); RR=0.50 (0.05-5.51) uterine scar dehiscence in subsequent pregnancy single: n=4/1609 (<1%); double: n=2/1624 (<1%); RR=2.01 (0.37-10.95) placenta previa in subsequent pregnancy single: n=5/1609 (<1%); double: n=4/1624 (<1%); RR=1.23 (0.33-4.57) morbidly adherent placenta in subsequent pregnancy single: n=0/1609 (<1%); double: n=2/1624 (<1%) hysterectomy in 6wks post partum in subsequent pregnancy	**Limitations** As in CORONIS 2013 **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
1 Sept 2011 - 30 Sept 2014 **Source of funding** UK Medical Research Council and the Department for International Development	single: n=32/1595; double: n=34/1616; RR=0.96 (0.59-1.54) **Inclusion criteria** women who participated in CORONIS 2013 study, with subsequent pregnancy in following 3 years **Exclusion criteria** As in CORONIS 2013			single: n=1/1610 (<1%); double: n=1/1624 (0%)	
Full citation Darj, E., Nordstrom, M. L., The Misgav Ladach method for cesarean section compared to the Pfannenstiel method, Acta Obstetricia et Gynecologica Scandinavica, 78, 37-41, 1999 **Ref Id** 930797 **Country/ies where the study was carried out** Sweden	**Sample size** n=50; randomly allocated n=25 to each group **Characteristics** age (mean, range): ML: 29.6 (21-40) years; Pfann: 29.3 (21-37) years GA (mean, range): ML: 38.6 (37-42) weeks; Pfann: 38.3 (37-42) weeks placenta previa: n=2/50 both randomly allocated to Misgav-Ladach group	**Interventions** **Misgav-Ladach**: incision: straight, not through subcutaneous fat; hysterotomy clsore: one layer; visceral and parental pertoneum: open; fascia closure: continuously; skin closure: 2-3 interrupted sutures, skin edges pinched together for 5-7 mins; sutures: 2 Vicryl, 1 Ethion **Pfannenstiel:** incision: curved, through subcutaneous fat; hysterotomy closure: two layers; visceral and parental peritoneum: closed; fascia closure: interrupted sutures; skin closure: continuous intracutaneous suture; sutures: 6 Vicryl	**Details** Antibiotics as standard: prophylactic antibiotics were not used Exteriorisation of uterus: in all cases Statistics used: Sample size was chosen to detect a difference of 10 minutes in mean operating time or a difference of 100 ml of bleeding, which could be of clinical importance, with 80% power at 5% significance level other: spinal anaesthesia in most, general anaesthesia in 2/50 (1/25 each)	**Results** Antibiotics required: n=0/25 in both groups Post-operative wound infection/endometritis: n=0/25 in both groups	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *randomly allocated to two groups and prospectively followed for three months (**LOW**)* • **Allocation concealment** *sealed opaque envelope designating the allocated method, was opened by the woman's husband before initiating the operation (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *woman's husband opened the envelope before the*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type RCT **Aim of the study** Evaluate the outcome of two different methods of elective caesarean section **Study dates** 1996 - 1997 **Source of funding** Not reported	**Inclusion criteria** women having their first C-Section, but could have delivered vaginally before **Exclusion criteria** previous abdominal operation				*procedure, unclear if woman know allocation (**UNCLEAR**)* • **Blinding of personnel:** *One surgeon, the author, performed all the procedures in the study. Unable to blind personnel to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *operating staff measured operation time and the amount of bleeding , midwives noted mobilisation and infection on the ward, scar appearance assessed by patient and midwife (**HIGH**)* **Attrition bias - Incomplete outcome data (for each outcome):** Women treated as allocated *(**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation EL-Gharib, Mohamed Nabih, Awara, Ahmad. M, Ultrasound Evaluation of the Uterine Scar Thickness after Single Versus Double Layer Closure of Transverse Lower Segment Cesarean Section, Journal of Basic and Clinical Reproductive	**Sample size** N=150; 75 per group **Characteristics** Maternal age: single 28.84±3.4 years; double 28.36±3.2 years GA at birth: single 39.11±0.7 weeks, double 39.16±0.7 weeks	**Interventions** Single layer closure of transverse lower segment c-section. A one-layer closure usually involves a single continuous, locking layer of absorbable suture (0 Vicryl sutures) Double layer closure of transverse lower segment c-section. A two-layer closure typically adds an imbricating layer of absorbable suture (0 Vicryl sutures)	**Details** Antibiotics as standard: Type of incision used: transverse lower segment Uterine closure: single v double layer Exteriorisation of uterus: not reported Suture material: absorbable sutures (0 Vicryl) Type of suture/stitch pattern: single: continuous	**Results** <u>Wound sepsis (as proxy for antibiotic requirement)</u> single n=3/75; double n=6/75	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: HIGH** • **Random sequence generation** *Not reported, just "randomly assigned" (**UNCLEAR**)* • **Allocation concealment** *All the participants' names were hidden and replaced by code numbers to maintain the privacy. After obtaining written consent and*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Sciences, 2, 42-45, 2013 **Ref Id** 939275 **Country/ies where the study was carried out** Egypt **Study type** RCT **Aim of the study** evaluate the uterine scar thickness by ultrasonography in women randomly assigned to one or two layer closure of the uterine incision after primary c-section **Study dates** July 2010 - June 2012 **Source of funding** Not reported	Birthweight: single 2.86±0.6 kg; double 1.6±0.9 kg **Inclusion criteria** Scheduled primary elective caesarean section **Exclusion criteria** • multiple gestations, • abnormalities of fetal heart rate, • polyhydramnios, • uterine malformation, • anterior placenta previa, • placenta accreta, • uterine or cervical fibroid, • fetal macrosomia, • any previous uterine operation • any medical disease that compromises wound healing eg. diabetes mellitus, collagen diseases or anaemia		locking layer; double: +imbricating layer Peritoneal closure: not reported Skin closure: not reported		*confirming entry into the study, each patient was assigned a treatment group by selection of the next consecutive envelope. (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** Not reported *(**UNCLEAR**)* • **Blinding of personnel:** The group-Allocation was revealed to the surgeon during the surgery just before the repair - unable to blind surgeon to allocation *(**HIGH**)* **Detection bias - Blinding of outcome assessment:** *Relevant outcome assessment not reported (**UNCLEAR**)* **Attrition bias - Incomplete outcome data (for each outcome):** All women included in the analysis *(**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Hauth, J. C., Owen, J., Davis, R. O., Transverse uterine incision closure: one versus two layers, American Journal of Obstetrics and Gynecology, 167, 1108-1111, 1992 **Ref Id** 930890 **Country/ies where the study was carried out** USA **Study type** RCT **Aim of the study** Determine if closure of low transverse uterine caesarean incision with one layer of suture results in less operating time, better homeostasis, and less infectious morbidity than a two-layer closure **Study dates**	n=906; single (one-layer): n=457; double (two-layer): n=449 **Characteristics** age: single closure: 24.2 years; double 24.6 years GA at birth: single: 38 weeks; double: 37.8 weeks Gestational hypertension: single: n=58/457 (13%); double: n=68/449 (15%) Placenta previa: single: n=5/457 (1.1%); double: n=4/449 (0.9%) **Inclusion criteria** Women undergoing caesarean section **Exclusion criteria** • a vertical or T uterine incision was required (n=46) • the operating team could not perform the assigned closure (n=32)	single (one) layer of uterine stitches, or two-layers of uterine stitches all other variables remained the same	Antibiotics as standard: not reported Type of incision used: low transverse incision Uterine closure: one or two layer closure Exteriorisation of uterus: not reported Suture material: no1 chromic catgut, 36 inches Type of suture/stitch pattern: single: continuous locking stitch; double: single + imbricating closure Peritoneal closure: not reported Skin closure: not reported Other detail: randomisation by computer-generated list of random numbers for one or two layer closure. Random assignments placed in sequentially numbers sealed envelopes, opaque to bright lights. Envelopes were opened before initiation of c-section to preclude operator bias (selection bias). Knowledge of allocation was allowed to provide correct number of sutures. Study was powered to 0.90 with alpha=0.05 to detect difference in endometritis as large as 18% vs 27%	single layer: n=457; double layer: n=449 Blood transfusion single: n=9/457 (2.0%); double: n=11/449 (2.5%) Postpartum endometritis (proxy for antibiotic requirement) - excludes women with chorioamnionitis in labour single: n=83/457 (22%); double: n=65/449 (18%)	**Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *computer generated randomisation (**LOW**)* • **Allocation concealment** *Envelopes were opened before initiation of c-section to preclude selection/operator bias (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *unclear if women were told of allocation, unlikely to affect outcomes (**LOW**)* • **Blinding of personnel:** *Envelopes were opened before initiation of c-section so the scrub nurse could lay out the appropriate number of sutures to be used (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *unclear how or who decided if or how many additional sutures were required, other outcomes unlikely to be affected by blinding (**UNCLEAR**)* **Attrition bias - Incomplete outcome data (for each outcome):** Included all women randomised who could be treated with allocation to one or two-layer closure in analysis: n=32 could not have assigned closure *(**HIGH**)*

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5th June 1989 - 6th July 1991 **Source of funding** Not reported	• incomplete data were available for outcomes (n=7) 85 exclusions equally distributed between groups				**Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation Nabhan, A. F., Long-term outcomes of two different surgical techniques for cesarean, International journal of gynaecology and obstetrics, 100, 69-75, 2008 **Ref Id** 931027 **Country/ies where the study was carried out** Egypt **Study type** RCT **Aim of the study** assess adhesion formation and other long-term outcomes of cesarean delivery by comparing 2 surgical techniques: (1)	**Sample size** n=600 for first-time caesarean section; 300 randomised to each group. of which n=124 (62 per group) were also analysed at repeat caesarean section - end point of the study was reached when the pre-designated number of women (determined at the beginning of the study) who underwent repeat cesarean delivery was achieved **Characteristics** Maternal age: modified: 27.2±0.5 years; standard 28.9±0.82 years **First c-section (n=600)** GA at birth: modified: 38.3±0.34 weeks; standard 37.9±0.61 weeks	**Interventions** (1) "standard": Pfannenstiel incision with development of a bladder flap and in situ suturing of the uterus in 2 layers, (2) "modified": Joel-Cohen incision without bladder flap formation and with exterior suturing of the uterus in 1 layer; modified Misgav Ladach technique	**Details** Antibiotics as standard: not reported Type of incision used: Pfannastiel (with bladder flap) vs Joel-Cohen-Stark/MML (no bladder flap) Uterine closure: Pfannastiel-Kerr (double) vs Joel-Cohen-Stark/MML (single) Exteriorisation of uterus: Pfannaenstiel-Kerr: in situ; Joel-Cohen/MML: exteriorisation Suture material: not reported Type of suture/stitch pattern: not reported Peritoneal closure: Pfanennstiel: closed visceral and parietal; Joel-Cohen/MML: not sutured Skin closure: Joel-Cohen: not closed unless more than 2cm subcut fat Statistics: a sample size of 88 women undergoing repeat cesarean delivery for a 2-sided test and alpha value of 0.05 would	**Results** **First c-section** Blood transfusion modified: n=0/300; standard: n=3/300 (1%) Wound infection requiring additional antibiotics modified: n=5/300 (1.7%); standard n=7/300 (2.3%) **Repeat c-section** Blood transfusion modified: n=0/62; standard: n=5/62 (8.1%) Wound infection requiring additional antibiotics modified: n=4/62 (6.5%); standard n=4/62 (6.5%)	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *randomly assigned to either the standard (Pfannenstiel) group or the modified (Joel-Cohen) group using a computer-generated randomization list drawn up by a statistician and contained in a set of numbered sealed envelopes.(**LOW**)* • **Allocation concealment** *.When a participant was found eligible and had consented to participate in the study, the numbered envelope was opened to determine the operative technique.(**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *Participants did not know which group they had been assigned to for the duration of the study. (**LOW**)*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Pfannenstiel incision with development of a bladder flap and in situ suturing of the uterus in 2 layers, versus (2) the Joel-Cohen incision without bladder flap formation and with exterior suturing of the uterus in 1 layer **Study dates** 2002 - 2007 **Source of funding** Not reported	Parity (primigravida): modified: n=167/300 (55.7%); standard n=192/300 (64%) Parity (multipara): modified n=133/300; standard n=108/300 **Repeat c-section (n=124)** Maternal age: modified: 28.2±0.4 years; standard 29.8±0.5 years GA at birth: 38.1±0.5 weeks; standard 38.3±0.3 weeks **Inclusion criteria** women with indication for cesarean delivery by lower segment cesarean **Exclusion criteria** Not reported		have a 0.80 power. The present study would have a 0.90 power with a sample size of 116 patients undergoing a repeat cesarean delivery		• **Blinding of personnel:** Unclear who had knowledge of allocation - unable to blind surgeon *(**HIGH**)* **Detection bias - Blinding of outcome assessment:** *No information, likely from case reports/medical records (**UNCLEAR**)* **Attrition bias - Incomplete outcome data (for each outcome):** *Analysis by intention-to-treat (**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation Ohel, G., Younis, J. S., Lang, N., Levit, A., Double-layer closure of uterine incision with visceral and parietal peritoneal closure: are they obligatory steps of routine cesarean sections?, Journal of	**Sample size** n=200 (100 per group) **Characteristics** Gravidity: study 3.1±1.9; control 2.9±1.7 Parity: study 1.8±1.6; control 1.7±1.6	**Interventions** Study group: uterine incision closed by **one layer of continuous non-locking suture**, visceral and parietal peritoneum were left open, fascia was closed using a continuous non-locking suture, and interrupted sutures placed on the skin	**Details** Antibiotics as standard: prophylactic antibiotics used in 84% (control group), 88% (study group) Type of incision used: low transverse or longitudinal abdominal incision; low transverse incision of uterus	**Results** Wound infection (proxy for antibiotic requirement) study (single layer): 4% (n=4/100) control (double layer): 3% (n=3/100)	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: HIGH** • **Random sequence generation** *Used ID number's final digit - evens allocated to study group, odds to control group (**HIGH**)*

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maternal-fetal medicine, 5, 366-369, 1996 **Ref Id** 931078 **Country/ies where the study was carried out** Israel **Study type** RCT **Aim of the study** examine the feasibility of a modified technique of caesarean section in which uterine incision is sutured in one layer and the visceral and parietal peritoneum are left open **Study dates** Not reported **Source of funding** Not reported	No previous c-section: study 69%; control 54% emergency c-section: study 65%; control 73% **Inclusion criteria** women undergoing caesarean section **Exclusion criteria** Not reported	Control group: uterus closed by 2 **continuous sutures in two layers**, the visceral peritoneum, the parietal peritoneum and fascia were each closed by continuous sutures. Interrupted sutures placed on the skin	Uterine closure: single vs double layer Exteriorisation of uterus: exteriorised in all cases Suture material: skin - Naylon; other layers - Vicryl (polyglactin 910) Type of suture/stitch pattern: continuous pattern (single - non locking) Peritoneal closure: open vs closed Skin closure: all had interrupted sutures Other: c-sections performed by residents in training and assisted by specialists in obstetrics and gynaecology. Anaesthesia was either general or regional. Operative technique similar until closure		• **Allocation concealment** *Allocation clear to anyone aware of ID number (**HIGH**)* **Performance bias: HIGH** • **Blinding of participants:** *No information (**UNCLEAR**)* • **Blinding of personnel:** *No information - unable to blind surgeon to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *No information (**UNCLEAR**)* **Attrition bias - Incomplete outcome data (for each outcome):** *all women included in analysis (**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation	**Sample size** n=400; 200 per group	**Interventions**	**Details**	**Results**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Poonam,, Banerjee, B., Singh, S. N., Raina, A., The Misgav Ladach method: a step forward in the operative technique of caesarean section, Kathmandu University Medical Journal, 4, 198-202, 2006 **Ref Id** 388049 **Country/ies where the study was carried out** Nepal **Study type** RCT **Aim of the study** compare the intra-operative and short term postoperative outcomes between the conventional and the Misgav-Ladach technique for caesarean section **Study dates** Sept 2001 - Sept 2004	**Characteristics** Maternal age: ML method 24.5 years (range 18-40); control 23.6 (18-40) years GA at birth: ML method 38.6 (38-42 weeks); control 38.5 (37-42 weeks) Primipara: ML method 54%; control 52% **Inclusion criteria** • Single pregnancies at term, undergoing caesarean section • emergency or elective c-section • after an estimated 37 full weeks of gestation **Exclusion criteria** • Multiple pregnancies • Previous caesarean section	**Group 1 Misgav Ladach Technique** 1. Joel Cohen's incision - a straight transverse incision about 3 cms below a line joining the anterior superior iliac spines. 2. Minimal use of instruments - Using the index and third fingers, abdominal wall layers were separated by stretching. Parietal peritoneum was also opened in the same way. 3. Manual lateral stretching of the uterine incision with exteriorization of the uterus. 4. **Single layer** uterine closure. 5. Non-closure of the visceral and parietal peritoneal layers. 6. Closure of the abdomen in two layers - Skin and Fascia **Group 2 Conventional method** 1. Pfannenstiel incision. 2. Use of instruments/sharp dissection while opening the abdomen and extending the incision on lower uterine segment. 3. **Double layer** uterine closure.	Antibiotics as standard: a broad spectrum antibiotic was used for all women Skin closure: skin was closed with non-absorbable suture material and inspected on the 3rd postoperative day. other: The total number of cases were performed by the same surgeon (senior resident) and assisted by junior residents on duty	Intra-operative transfusion *Reported but not relevant to intervention which occurs at closing, only post-operative transfusion data used in analysis* Post-operative transfusion ML method: n=2/200; control: n=10/200 Wound infection - abdominal wound dehiscence (proxy for antibiotic requirement) ML method: n=2/200; control n=13/200	**Risk of Bias assessed using Cochrane ROB tool** **Selection bias: UNCLEAR** • **Random sequence generation** *"The patients under study were divided into two groups by randomization" - no information regarding randomisation of concealment (**UNCLEAR**)* • **Allocation concealment** *No information regarding allocation concealment (**UNCLEAR**)* **Performance bias: HIGH** • **Blinding of participants:** *No information (**UNCLEAR**)* • **Blinding of personnel:** *No information unable to blind surgeon to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *No information (**UNCLEAR**)* **Attrition bias - Incomplete outcome data (for each outcome):** All women analysed as allocated *(**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported		4. Closure of the abdomen in layers except for the peritoneum.			
Full citation Sood, Atal Kumar, Single versus double layer closure of low transverse uterine incision at cesarean section, The Journal of Obstetrics and Gynecology of India, 55, 231-236, 2005 **Ref Id** 939274 **Country/ies where the study was carried out** India **Study type** RCT **Aim of the study** assess intraoperative and postoperative morbidity following single layer closure of low transverse uterine incision at cesarean section as compared to double layer closure	**Sample size** n=208; single layer n=102, double layer n=106 **Characteristics** Maternal age: single 26.5±4.5 years; double 25.4±3.5 years parity: single 2.1±0.9, double 1.9±0.6 GA at birth: single 38.2±1.5 weeks, double 37.8±1.8 weeks **Inclusion criteria** Emergency or elective caesarean section All women were eligible for the study, regardless of indication of cesarean delivery, type of skin incision, medical complications, high risk factors, and history of previous cesarean section	**Interventions** single layer: uterine closure was done with continuous nonlocking No.1 polyglactin double layer: an additional imbricating non-locking suture of the same material was employed.	**Details** Antibiotics as standard: All women received prophylactic antibiotics unless already receiving parenteral antibiotics. Cefazoline 2 g was given after cord clamping Type of incision used: Both Pfannenstiel and subumbilical midline incisions were used, and all uterine incisions were low transverse type Uterine closure: single or double layer Exteriorisation of uterus: exteriorised in all women after delivery of placenta Suture material: no1 polyglactin Type of suture/stitch pattern: continuous, non-locking Peritoneal closure: visceral and parietal peritoneum not closed Skin closure: rectus fascia "approximated" with no1 polypropylene, skin "approximated" with subcuticular closure Statistics used: A sample size and power analysis	**Results** Wound infection (proxy for antibiotic requirement) single layer: n=4/102 (3.9%); double: n=9/106 (8.5%); OR=0.43 (95%CI 0.13-1.47)	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *Randomisation was by computer generated random numbers (**LOW**)* • **Allocation concealment** *the randomised allocations were kept secure in sealed envelopes, which were opened in the operation room (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** Treatment allocation was disclosed neither to the nursing or medical staff providing postoperative care, nor to the women *(**LOW**)* • **Blinding of personnel:** *the randomized allocations were kept secure in sealed envelopes, which were opened in the operation room. Treatment allocation was disclosed neither to the nursing or medical staff providing postoperative care, nor*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates October 2001 - December 2003 **Source of funding** Not reported	**Exclusion criteria** None reported		were undertaken prior to the study. 108 women were required in each arm to show a reduction in febrile morbidity from 21% to 7% between double and single layer closure (Power = 0.80, alpha =0.05 and beta= 0.2).		*to the women. - not possible to blind surgeon to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** Relevant outcomes assessed by medical staff - *Treatment allocation was disclosed neither to the nursing or medical staff providing postoperative care, nor to the women (**LOW**)* **Attrition bias - Incomplete outcome data (for each outcome):** All women included in analysis *(**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**
Full citation Xavier, P., Ayres-De-Campos, D., Reynolds, A., Guimarães, M., Costa-Santos, C., Patrício, B., The modified Misgav-Ladach versus the Pfannenstiel-Kerr technique for cesarean section: a randomized trial, Acta Obstetricia et Gynecologica Scandinavica, 84, 878-882, 2005 **Ref Id** 931257	**Sample size** randomised n=162; MML n=88, PK n=74 analysed: MML n=77, PK n=69 n=16 women (9.9%) were excluded after randomisation, 12 because it was not possible to contact them after discharge from hospital and the remaining 4 because they left the hospital before the third postoperative day (11 in the MML group and five in the PK group).	**Interventions** **modified Misgav-Ladach (MML)**: Closure of the uterine incision is accomplished with a **one-layer continuous** #1 poliglactin 910 (Vicryl1) suture, using additional hemostatic stitches if required. After the inspection of the peritoneal cavity and removal of accessible blood and clots, the visceral and parietal peritoneum is left unsutured. The rectus muscles, subfascial space, and subcutaneous tissue are inspected forhemostasis, and the rectus sheath is closed using a continuous #1 polyglactin 910 suture	**Details** Antibiotics as standard: Prophylactic antibiotics were administered to all women after umbilical cord clamping: 2 g of intravenous (i.v.) ampicillin or 500 mg of i.v. erythromycin in patients with hypersensitivity to penicillins Type of incision used: Pfannenstiel incision Exteriorisation of uterus: optional in MML Statistics used: The planned study of 160 patients had an 80%	**Results** <u>Post-operative antibiotics</u> MML (single): n=73/77 (95%); PK (double): n=64/69 (93%)	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *patient were allocated to one of the two study arms according to a sequence of computer-generated random numbers (**LOW**)* • **Allocation concealment** *Pre-allocation concealment was assured by an individual strip of black tape removed from the computer-generated list at the time of randomisation (**LOW**)*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Portugal **Study type** RCT **Aim of the study** compare intraoperative and short-term postoperative outcomes between the Pfannenstiel–Kerr and the modified Misgav-Ladach (MML) techniques for cesarean section **Study dates** Not reported **Source of funding** Not reported	**Characteristics** Maternal age: MML 28 years (range 19-42); PK 28 years (18-41) GA at birth (median): MML 38 weeks (27-42); PK 38 weeks (29-42) Parity (one): MML n=47/77 (61%); PK n=39/69 (57%) Parity (two): MML n=19/77 (25%); PK n=21/69 (30%) **Inclusion criteria** scheduled for elective or emergency cesarean section by one of three experienced surgeons **Exclusion criteria** • a previous midline infraumbilical skin incision, • axillary temperature exceeding 37.5 C in the 48 hr before surgery, • antibiotic use in the preceding week	**Pfannenstiel-Kerr:** Closure of the uterine incision is accomplished with a **two-layer continuous** #1 polyglactin 910 suture, using additional hemostatic stitches if required. The visceral peritoneum is closed with a continuous #2/0 polyglactin 910 suture. After the inspection of the peritoneal cavity and aspiration of all accessible blood and clots, the parietal peritoneum is closed in a similar fashion. The rectus muscles, subfascial space, and subcutaneous tissue are checked for hemostasis, and the rectus sheath is closed with a continuous #1 polyglactin 910 suture.	power to detect a difference between the two techniques of 20% in bowel restitution by the second postoperative day (assuming 70% and 50% for MML and PK, respectively), at the 5% significance level.		**Performance bias: HIGH** • **Blinding of participants:** *No information (**UNCLEAR**)* • **Blinding of personnel:** *No information - unable to blind surgeon to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *The staff in charge of the postoperative period was unaware of the surgical technique employed in individual patients. Analgesic requirements, antibiotic use, and day of bowel restitution were obtained from the hospital notes and confirmed with patients on the fourth postoperative day (**LOW**)* **Attrition bias - Incomplete outcome data (for each outcome):** *n=16 women (9.9%) were excluded after randomisation, 12 because it was not possible to contact them after discharge from hospital and 4 because they left the hospital before the third postoperative day (11 in the MML group and five in the PK group) (**LOW**)* **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Yasmin, S., Sadaf, J., Fatima, N., Impact of methods for uterine incision closure on repeat caesarean section scar of lower uterine segment, Journal of the college of physicians and surgeons--pakistan : JCPSP, 21, 522-526, 2011 **Ref Id** 931261 **Country/ies where the study was carried out** Pakistan **Study type** RCT **Aim of the study** compare the effect of different suturing techniques in repeat caesarean section in terms of scar thickness, blood loss, operative time and scar dehiscence at the time of next caesarean section.	**Sample size** n=90 randomised; 30 per group single n=30; double n=60* **both groups of double layer suturing have been combined for purposes of the review* **Characteristics** Maternal age (range): 20-35 years Parity (range): 1-4 GA at birth (range): 37-40 weeks **Inclusion criteria** • singleton term pregnancy, • parity less than 5, • history of previous caesarean section (one to three) **Exclusion criteria** • multiple gestation, • polyhydramnios, • parity greater than 5,	**Interventions** **A - one layer closure**: had their transverse uterine incision closure in one layer with running locking sutures penetrating the full thickness of myometrium with chromic catgut no. 2. **B - two layer closure*:** had an initial closure identical to the one layer closure as above. An additional layer of chromic catgut no. 2 was used to imbricate the first layer in a continuous non-locking suture. **C - modified two layer closure***: had first layer closure by interrupted horizontal mattress sutures taking full thickness of decidua and myometrium. The previous scar tissue was not excised. Care was taken to select the site of each stitch and to avoid withdrawing the needle once it penetrated the myometrium. This minimized the perforation of unligated vessels and subsequent bleeding. The second layer folded muscles over the first layer of sutures in running non-locking sutures. **both groups of double layer suturing have been combined for purposes of the review*	**Details** Antibiotics as standard: All the patients received first dose of first generation cephalosporin antibiotic at umbilical cord clamping. These intravenous antibiotics were continued to all the patients for 24 hours as per hospital protocol Type of incision used: low transverse Uterine closure: A: single layer; B: double layer; C: modified 2 layer Exteriorisation of uterus: not reported Suture material: A&B: chromic catgut no2 Type of suture/stitch pattern: A: one layer running locking sutures penetrating full myometrium; B: "A" + imbricating continuous nonlocking sutures; C: 1st layer interrupted horizontal mattress sutures + 2nd layer folded muscles Peritoneal closure: not reported Skin closure: not reported	**Results** Wound sepsis requiring additional antibiotics n=0/90 (no cases in each group)	**Limitations** **Risk of Bias assessed using Cochrane ROB tool** **Selection bias: LOW** • **Random sequence generation** *random allocation was performed using pre-made allocation cards (**LOW**)* • **Allocation concealment** *each patient was asked to pick the allocation cards from a box (**LOW**)* **Performance bias: HIGH** • **Blinding of participants:** *No information - suggestion participants were aware as they picked the allocation card (blinded) (**UNCLEAR**)* • **Blinding of personnel:** *The group allocation was revealed to the surgeon during the surgery just before the uterine incision closure - unable to blind surgeon to allocation (**HIGH**)* **Detection bias - Blinding of outcome assessment:** *additional haemostatic sutures were placed at the discretion of the operating surgeon and the number of the additional sutures was recorded - aware of allocation (**HIGH**)* **Attrition bias - Incomplete outcome data (for each outcome):** All patients

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Study dates June 2005 - June 2010 **Source of funding** Not reported	• maternal diabetes, • anaemia • connective tissue disorder				treated per allocation, all 90 cases analysed as per allocation ***(LOW)*** **Reporting bias - Selective reporting:** *No access to protocol (**UNCLEAR**)* **Other information**