D.18 Treatment and secondary prevention for distal intestinal obstruction syndrome

Item	Details
Issue in the scope	Management of distal ileal obstruction syndrome.
Review question in the scope	What are the effective strategies for treatment and secondary prevention of distal ileal obstruction syndrome?
Review question for the protocol	What are the effective strategies for treatment and secondary prevention of distal ileal obstruction syndrome?
Objective	This review aims to identify the effective strategies of primary treatment (acute treatment) in those with a diagnosis of CF and DIOS. Additionally, this review aims to identify the effective strategies for the secondary prevention of DIOS.
Language	English
Study design	• Systematic reviews of RCTs • RCTs • Conference abstracts of RCTs (Only if RCTs unavailable and the quality assessment of abstracts will conducted based on the available information and if necessary the authors of abstracts will be contacted). • Comparative cohort studies (only if RCTs unavailable or limited data to inform decision making)
Population and directness	Primary prevention Infants, children, young people and adults with CF, diagnosed clinically and by sweat test or genetic testing and DIOS based on clinical diagnosis with or without imaging studies. Secondary prevention Infants, children, young people and adults with CF, diagnosed clinically and by sweat test or genetic testing and one or more previous episodes of DIOS. Population size and indirectness: • No sample size specification. • Studies with indirect populations will not be included
Stratified, subgroup and	Stratified analysis: • primary treatment

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adjusted analyses	• secondary prevention Sensitivity analysis: including and excluding studies with a high risk of bias. Subgroup analysis: • None identified
Intervention	Primary (acute) interventions • osmotic laxative containing polyethylene glycol (macrogol)(movicol) • sodium meglumine diatrizoate (Gastrografin) • N-acetyl cysteine • Lactulose • Stimulant laxative e.g. senna/ sennosides, sodium picosulfate • Enemas (phosphate, Gastrografin) • Surgery for example distal ileal resection Secondary prevention interventions • Osmotic laxative containing polyethylene glycol (macrogol) • Lactulose • Pancreatic enzyme replacement therapy (PERT) • N-acetyl cysteine • Sodium meglumine diatrizoate (Gastrografin) Administration of oral treatments may also be via nasogastric tube and this is included within the protocol.
Comparison	• Treatment 1 vs Treatment 2 • Placebo • No treatment
Outcomes	Primary treatment 1) Reduction in clinical manifestations including: ○ Abdominal pain ○ Vomiting ○ Distention ○ Abdominal mass (also by radiological imaging X-ray/ultrasound) ○ Stool frequency 2) Adverse events from treatment ○ abdominal pain ○ flatulence ○ nausea or vomiting ○ diarrhoea ○ fluid overload ○ bowel perforation ○ bowel ischemia ○ hypotension 3) Patient satisfaction (including adherence to treatment) 4) Duration of hospital stay (days) 5) Treatment failure (need for surgery) 6) Adverse events from surgery ○ Mortality ○ Perforation/Infection Secondary prevention Outcomes 1, 2, 3 above and 4) Recurrence of DIOS 5) Admission to hospital Note: change from baseline will be prioritised over absolute values

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Item	Details
Importance of outcomes	Critical outcomes for decision making: Primary treatment • Reduction in clinical manifestations • Adverse events for treatment/ surgery • Treatment failure Secondary treatment • Reduction in clinical manifestations • Adverse events for treatment • Recurrence of DIOS
Setting	Any healthcare setting where NHS care is delivered (primary, secondary, tertiary or community).
Search strategy	Sources to be searched: Medline, Medline In-Process, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Reviews of Effectiveness, Health Technology Database, Embase Limits (e.g. date, study design): Limit to RCTs and systematic reviews in the first instance but download all study designs. Apply standard exclusions and English language filters. Supplementary search techniques: No supplementary search techniques will be used. See appendix E.13 for full strategies
Review strategy	Appraisal of methodological quality: • The methodological quality of each study will be assessed using an appropriate checklist as per NICE guidelines manual (The Cochrane Risk of Bias tool for RCTs and the Newcastle and Ottawa scale for observational studies). • The quality of the evidence will be assessed by GRADE for each outcome according to the process described in the NICE guidelines manual (2014). Synthesis of data: • Meta-analysis will be conducted where appropriate. If comparative cohort studies are included, the minimum number of events per covariate to be recorded to ensure accurate multivariate analysis. • Final and change scores will be pooled and if any study reports both, change scores will be used in preference over final scores. • If studies only report p-values from parametric analyses, and 95% CIs cannot be calculated from other data provided, this information will be plotted in GRADE tables, but evidence may be downgraded. • If studies only report p-values from non-parametric analyses, this information will be plotted in GRADE tables without downgrading the evidence, as imprecision cannot be assessed for non-parametric analyses. Minimal important differences (MIDs): Primary treatment • Reduction in clinical manifestations: any change will be considered clinically significant • Treatment failure: GRADE default • Adverse events for treatment/ surgery: GRADE default Secondary treatment • Reduction in clinical manifestations: any change will be considered clinically significant • Recurrence of DIOS: GRADE default • Adverse events for treatment/ surgery: GRADE default Default MIDs: 0.8 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes.

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	• Review process: • A list of excluded studies will be provided following weeding. Evidence tables and an evidence profile will be used to summarise the evidence.
Equalities	• Psychological and behavioural issues are more likely in people with a lower socioeconomic status • Gender- outcomes are worse for women although there is no evidence that this is a consequence of difference in care • Geographical issues – care is given through specialist centres and this may be a problem if a person with CF is living in an isolated location.
Notes/additional information	None.

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