

Gosney, 2006

Bibliographic Reference

Gosney, M.; Martin, M. V.; Wright, A. E.; The role of selective decontamination of the digestive tract in acute stroke; Age Ageing; 2006; vol. 35 (no. 1); 42-7

Study details

Secondary publication of another included

No additional information.

study- see primary study for details	
Other publications associated with this study included in review	No additional information.
Trial name / registration number	No additional information.
Study type	Randomised controlled trial (RCT)
Study location	England.
Study setting	Acute stroke assessment units of three hospitals in the northwest of England.
Study dates	January 2001 and 2003.
Sources of funding	This project was funded by the Northwest Zonal Research and Development. One investigator was employed as a research nurse by the funding body.
Inclusion criteria	People within 24 hours of admission to hospital following a first acute stroke.
Exclusion criteria	People receiving antibiotic or steroid medication, including inhaled steroids, or having had a previous stroke.
Recruitment / selection of participants	No additional information.
Intervention(s)	Oral hygiene intervention (four times a day) N=103 Orobase gel, containing 2% (w/v) colistin, 2% (w/v) polymyxin E and 2% (w/v) amphotericin B, 500mg applied to the mucous membranes of the mouth four times daily for 2-3 weeks (2 weeks if they had a safe swallow, 3 weeks if they had an unsafe swallow).
Comparator	Placebo N=100 Placebo gel applied four times daily for 2-3 weeks (2 weeks if they had a safe swallow, 3 weeks if they had an unsafe swallow).

Number of participants	203.
Duration of follow-up	3 months in total.
Additional comments	No additional information.
Subgroup 1: Severity (as stated by category or as measured by NIHSS scale)	Not stated/unclear
Subgroup 2: Type of stroke (using the Bamford scale)	Not stated/unclear
Subgroup 3: Dysphagia at baseline	Mixed
Subgroup 4: Type of intervention	Other Antimicrobial oral gel
Subgroup 5: People who are nil-by-mouth at baseline	Not stated/unclear
Subgroup analysis - further details	No additional information.

Study arms

Oral hygiene intervention (four times a day) (N = 103)

Orobase gel, containing 2% (w/v) colistin, 2% (w/v) polymyxin E and 2% (w/v) amphotericin B, 500mg applied to the mucous membranes of the mouth four times daily for 2-3 weeks (2 weeks if they had a safe swallow, 3 weeks if they had an unsafe swallow).

Placebo (Usual care) (N = 100)

Placebo gel applied four times daily for 2-3 weeks (2 weeks if they had a safe swallow, 3 weeks if they had an unsafe swallow). For this analysis this will be treated as usual care.

Characteristics

Arm-level characteristics

Characteristic	Oral hygiene intervention (four times a day) (N = 103)	Placebo (Usual care) (N = 100)
% Female	49	48
Nominal		
Mean age (SD)	16 to 96	45 to 92
Range		
Mean age (SD)	70.5 (NR to NR)	73.3 (NR to NR)
Median (IQR)		
Ethnicity	NR	NR
Nominal		

Characteristic	Oral hygiene intervention (four times a day) (N = 103)	Placebo (Usual care) (N = 100)
Comorbidities	NR	NR
Nominal		
Severity	NR	NR
Nominal		
Type of stroke	NR	NR
Nominal		
Dysphagia at baseline	25	33
Nominal		
People who are nil-by-mouth at baseline	NR	NR
Nominal		

Outcomes

Study timepoints

- Baseline
- 3 week (During inpatient stay. Additional information about mortality was reported at 3 months, but this was not reported by group so it was unable to extract this information.)

Oral hygiene intervention (four times a day) compared to usual care at ≤3 months - dichotomous outcomes

Outcome	Oral hygiene intervention (four times a day), Baseline, N = 103	Oral hygiene intervention (four times a day), 3 week, N = 103	Placebo (Usual care), Baseline, N = 100	Placebo (Usual care), 3 week, N = 100
Mortality Nominal	NR	9	NR	11
Occurrence of pneumonia Nominal	NR	1	NR	7

Mortality - Polarity - Lower values are better

Occurrence of pneumonia - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT**Oral hygiene intervention (four times a day) compared to usual care at ≤3 months - dichotomous outcomes - Mortality - Nominal - Oral hygiene intervention (four times a day) - Placebo - t3**

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

Oral hygiene intervention (four times a day) compared to usual care at ≤3 months - dichotomous outcomes - Occurrence of pneumonia - Nominal - Oral hygiene intervention (four times a day) - Placebo - t3

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable