Kim, 2014

Bibliographic Reference	Kim, E. K.; Jang, S. H.; Choi, Y. H.; Lee, K. S.; Kim, Y. J.; Kim, S. H.; Lee, H. K.; Effect of an oral hygienic care program for stroke patients in the intensive care unit; Yonsei Medical Journal; 2014; vol. 55 (no. 1); 240-6

Study details

Secondary publication of another included study- see primary study for details	No additional information.
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	South Korea (Daegu)
Study setting	People admitted to the intensive care unit of the neurosurgery department of a university hospital.
Study dates	No additional information.
Sources of funding	This research was supported by research grants from Yeung-nam University in 2010.
Inclusion criteria	First-ever stroke; had six or more teeth.
Exclusion criteria	Sign of infection with any contagious pathogen.
Recruitment / selection of participants	No additional information.
Intervention(s)	Oral hygiene intervention (once per day) N=45 Oral hygienic management administered by one dentist once every day for an average of 2.2 weeks (range 1-5 weeks). For people without consciousness, a mouth gag for dental care was used to keep the mouth open. A children's toothbrush and an interdental toothbrush were used for removal of plaque on the teeth, while a tongue cleaner was used to get rid of plaque on the tongue. Then, gauze soaked with 0.5% chlorohexidine was used to clean oral mucosa and tooth surfaces and to remove foreign bodies inside the mouth.
Comparator	Usual care N=45 No specific oral hygiene intervention.
Number of participants	90
Duration of follow-up	For the duration of their ICU stay (mean 2.2 weeks, range 1-5 weeks). Will consider the mean follow up time for analysis.
Additional comments	No additional information.
Subgroup 1: Severity (as stated by category or as	Not stated/unclear

measured by NIHSS scale)	
Subgroup 2: Type of stroke (using the Bamford scale)	Not stated/unclear
Subgroup 3: Dysphagia at baseline	Not stated/unclear
Subgroup 4: Type of intervention	Professional tooth cleaning
Subgroup 5: People who are nil-by-mouth at baseline	Not stated/unclear
Subgroup analysis - further details	Type of stroke: Reported infarction (6) compared to haemorrhage (50).

Study arms

Oral hygiene intervention (once per day) (N = 45)

Oral hygienic management administered by one dentist once every day for an average of 2.2 weeks (range 1-5 weeks). For people without consciousness, a mouth gag for dental care was used to keep the mouth open. A children's toothbrush and an interdental toothbrush were used for removal of plaque on the teeth, while a tongue cleaner was used to get rid of plaque on the tongue. Then, gauze soaked with 0.5% chlorohexidine was used to clean oral mucosa and tooth surfaces and to remove foreign bodies inside the mouth.

Usual care (N = 45)

No specific oral hygiene intervention.

Characteristics

Arm-level characteristics

Characteristic	Oral hygiene intervention (once per day) (N = 45)	Usual care (N = 45)
% Female Sample size	n = 16 ; % = 55.2	n = 13 ; % = 48.1
Mean age (SD) Mean (SD)	57.38 (14.22)	56.15 (14.55)
Ethnicity Nominal	NR	NR
Comorbidities Nominal	NR	NR
Severity Nominal	NR	NR
Infarct Sample size	n = 3 ; % = 10.3	n = 3 ; % = 11.1
Haemorrhagic Sample size	n = 26 ; % = 89.7	n = 24 ; % = 88.9
Dysphagia at baseline Nominal	NR	NR

Characteristic	Oral hygiene intervention (once per day) (N = 45)	Usual care (N = 45)
People who are nil-by-mouth at baseline Nominal	NR	NR

Outcomes

Study timepoints
- Baseline
- 2 week (Will be included as ≤3 months)

Oral hygiene intervention (once per week) compared to usual care at ≤3 months - dichotomous outcomes

Outcome	Oral hygiene intervention (once per day), Baseline, N = 45	Oral hygiene intervention (once per day), 2 week, N = 29	Usual care, Baseline, N = 45	Usual care, 2 week, N = 27
Presence of oral disease (oral candidiasis) - tongue Including anyone with candida >grade 1. Intervention: Grade 1 = 6, grade 2 = 3, grade 3 = 14. Control: Grade 1 = 6, grade 2 = 9, grade 3 = 9. Nominal	NR	23	NR	24
Presence of oral disease (oral candidiasis) - saliva Including anyone with candida >grade 1. Intervention: Grade 1 = 6, grade 2 = 6, grade 3 = 10. Control: Grade 1 = 6, grade 2 = 7, grade 3 = 7. Nominal	NR	22	NR	20

Outcome	Oral hygiene intervention (once per day), Baseline, N = 45	Oral hygiene intervention (once per day), 2 week, N = 29	Usual care, Baseline, N = 45	Usual care, 2 week, N = 27
Mortality Reported in study as 'expiration' Nominal	NR	2	NR	3

Presence of oral disease (oral candidiasis) - tongue - Polarity - Lower values are better

Presence of oral disease (oral candidiasis) - saliva - Polarity - Lower values are better

Mortality - Polarity - Lower values are better

Oral hygiene intervention (once per week) compared to usual care at ≤3 months - continuous outcomes

Outcome	Oral hygiene intervention (once per day), Baseline, N = 45	Oral hygiene intervention (once per day), 2 week, N = 29	Usual care, Baseline, N = 45	Usual care, 2 week, N = 27
Presence of oral disease (gingivitis - gingival index) Continuous outcome. Will be downgraded due to indirectness. Scale range: 0-3. Mean (SD)	1.54 (0.47)	0.47 (0.64)	1.3 (0.53)	1.6 (0.61)
Length of hospital stay (length of ICU admission) (days) Downgrade for indirectness as only reporting ICU admission length Mean (SD)	NA (NA)	15.69 (10.02)	NA (NA)	18.15 (8.07)

Presence of oral disease (gingivitis - gingival index) - Polarity - Lower values are better

Length of hospital stay (length of ICU admission) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Oralhygieneintervention(onceperweek)comparedtousualcareat≤3months-dichotomousoutcomes-Presenceoforaldisease(oralcandidiasis)-tongue-Nominal-Oral hygiene intervention (once per day)-Usual care-t2

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

Oralhygieneintervention(onceperweek)comparedtousualcareat≤3months-dichotomousoutcomes-Presenceoforaldisease(oralcandidiasis)-saliva-Nominal-Oral hygiene intervention (once per day)-Usual care-t2

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

Oralhygieneintervention(onceperweek)comparedtousualcareat≤3months-dichotomousoutcomes-Mortality-Nominal-Oral hygiene intervention (once per day)-Usual care-t2

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

Oralhygieneintervention(onceperweek)comparedtousualcareat≤3months-continuousoutcomes-Presenceoforaldisease(gingivitis-gingivalindex)-MeanSD-Oral hygiene intervention (once per day)-Usual care-t2

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable *(Downgraded due to outcome indirectness (continuous scale for an outcome prespecified to be dichotomous in the protocol))*

Oralhygieneintervention(onceperweek)comparedtousualcareat≤3months-continuousoutcomes-Lengthofhospitalstay(lengthofICUadmission)-MeanSD-Oral hygiene intervention (once per day)-Usual care-t2

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Partially applicable *(Downgraded due to outcome indirectness (length of ITU stay rather than length of hospital admission))*