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Brushing the teeth 4 times a day rather than twice per day reduces the amount of bacterial colonisation in the upper respiratory tract of ventilated patients in ITU

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/09/2013	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0112173777

Study information

Scientific Title

Study objectives
Patients on ventilators in intensive therapy units (ITUs) are dependent on nursing staff for oral hygiene. Early onset ventilator associated pneumonia occurs 48-72 hours after insertion of an endotracheal tube. There are several factors involved in this. One is poor oral hygiene. This is because bacteria contributing to pneumonia may colonise teeth. These bacteria are then aspirated into the chest. Pneumonia may follow this. The principle question is whether improving oral hygiene by brushing the teeth more frequently than normal will reduce the number of bacteria in the upper airway. If so, it may reduce rates of pneumonia. Hypothesis: good oral hygiene reduces colonisation of the airway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health: Ventilator associated pneumonia

Interventions
Twenty patients will be randomised to one of two groups. Twenty envelopes will contain ten labels for each group. Either control or enhanced. These will be shuffled into a random order, then labelled 1 to 20. As each patient is admitted, their group will be decided by sequential envelopes containing the randomised group name. Envelope one will be used first, then envelope two and so forth.

The control group patients will receive the ITC standard oral hygiene. That is, teeth brushed twice per day, in the morning and evening with a small toothbrush and toothpaste. The toothbrush and toothpaste will be identical for each patient. Oropharyngeal suction will be performed by nursing staff as required using a Yankaur suction device. Foam swabs wet with water will be used in between times for comfort.

The enhanced care group will receive the standard oral care as described, but will have their teeth brushed four times per day at 6 hourly intervals. Oropharyngeal suction will be provided as required as will wet foam swabs for comfort. If untoward bleeding of the gums occurs in participants, they may be withdrawn from the trial.
Each patient will have an oral/dental swab taken on admission. The sterile swab will be wiped around all facets of the teeth and gums that are accessible. The participant will also have a sputum specimen taken. This will be aspirated from the endotracheal tube using a closed system suction device and specimen trap. The participant will be preoxygenated before the procedure to prevent instability of their condition. The procedure will only be carried out at a time when aspiration of sputum from the chest is already indicated as part of the normal treatment. Both these procedures will be carried out by registered physiotherapists who will be blinded to the treatment group of the participant. Specimens will be anonymised as each patient will be allocated a number at the beginning of the study. The specimens will be sent to the microbiology dept. for analysis before being destroyed.

Oral swabs and sputum samples will be collected from each participant on day 0, day 3, day 6, and day 10 for analysis. Nursing staff will be trained in the method of oral hygiene to be used. Physiotherapists will be trained in the specific way in which to take swabs and sputum samples in order to standardise the procedure. Both groups of staff perform these procedures as part of their normal job.

Patients will be followed for a maximum of 10 days after inclusion, Standard demographic information will be recorded including gender, age, diagnosis requiring ITU and ventilatory support. The severity of illness score will also be noted (APACHE 11 score). Throughout the days temperature will be recorded at 4 hourly intervals as normal. Any spike in temperature above 38 degrees centigrade will be noted, as will any change in antibiotic therapy. A score of the condition of the patient's mouth will also be made(tool to be confirmed).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Levels of bacterial colonisation in the upper respiratory tract over the ten day period measured as numbers of colony forming units. Comparison between the control and enhanced care group.

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/11/2005

Completion date

15/03/2006

Eligibility

Key inclusion criteria
Eligible patients are to be enrolled between 12/05 and 03/06 from Epsom and St Helier Hospital ITUs. The study will be a prospective blind randomised controlled trial. Approval from the Research Ethics Committee and Research and Development are being sought.

Patients admitted to the ITU for mechanical ventilation will be invited to join the study as long as they fulfill the following criteria: all adult patients, male and female aged 18 to 95 with written consent. This may be obtained from the participant or from a legal representative or next of kin. Participants must have been intubated within the hospital. However, if intubated in another hospital they may be included as long as they arrive in the ITU within 12 hours of intubation. Participants must not be endentulous or have a tracheostomy tube. Patients with both medical and surgical diagnosis will be included but their condition must suggest an expected admission period of more that 8 days.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Edentulous patients
2. Patients with a facial injury
3. Patients with a tracheostomy tube

Date of first enrolment
17/11/2005

Date of final enrolment
15/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Epsom & St Helier University Hospital NHS Trust
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK) - NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration