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Use of chlorhexidine gluconate 0.2% oral rinse (CHX) to reduce the incidence of nosocomial lower respiratory tract infections in intubated ICU adult patients

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
11/12/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
N0185116743

Study information

Scientific Title

Use of chlorhexidine gluconate 0.2% oral rinse (CHX) to reduce the incidence of nosocomial lower respiratory tract infections in intubated ICU adult patients

Study objectives
Does the use of chlorhexidine gluconate 0.2% mouthwash reduce the incidence of nosocomial lower respiratory tract infection in adult patients who are intubated and receiving mechanical ventilation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Respiratory: Lower respiratory tract infection

Interventions
We propose to administer 15 ml chlorhexidine gluconate or placebo to the buccal, pharangeal, gingival tongue, roof of mouth and tooth surfaces with a sponge swab twice daily to intubated patients who are predicted to require mechanical ventilation. Broncheoalveolar lavage specimen will be sent for culture every 48 h and the following clinical observations will be recorded daily - white cell count, sputum appearance, temperature and chest X-ray changes. The study ends once the patient is extubated but the observations will be recorded for a further 7 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chlorhexidine gluconate

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date

31/03/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2002

Date of final enrolment
31/03/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Plymouth Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration