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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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 11/12/2014	**Condition category** Respiratory	

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

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

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2002

Completion date
31/03/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Plymouth Hospitals NHS Trust (UK)

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