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 Recruitment status Prospectively r	registered
12/09/2003 No longer recruiting [] Protocol	
Registration date Overall study status [] Statistical anal	ysis plan
12/09/2003 Completed [] Results	
Last Edited Condition category [] Individual part	icipant data
11/12/2014 Respiratory [] Record update	d in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

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