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A study comparing a suspension of Lactobacillus plantarum 299 with chlorhexidine for oral care in intubated mechanically ventilated patients in intensive care

Submission date 22/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/01/2008	**Overall study status** Completed	
Last Edited 31/12/2020	**Condition category** Oral Health	

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
NCT01105819

Secondary identifying numbers
PROHYG

Study information

Scientific Title
A study comparing a suspension of Lactobacillus plantarum 299 with chlorhexidine for oral care in intubated mechanically ventilated patients in intensive care

Study objectives
The probiotic bacterium Lactobacillus plantarum 299 reduces growth of pathogenic bacteria in the oral cavity in intubated patients to the same extent as chlorhexidin but is a better ecologic alternative.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Final ethical approval was obtained from the Human Ethics Committee at the Lund University on the 29th September 2003 (ref: LU 346-03)

Study design
Pilot, prospective, open, randomised controlled study.

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
Growth of pathogenic bacteria in the oral cavity

Interventions
Randomisation is carried out in groups of 10 participants. 20 participants are allocated to each of the two groups.

A The control group will receive the standard oral care of the department (general ICU, Lund University Hospital).
This includes suction of secretions, brushing of teeth cleansing of the oral cavity with swabs soaked with a chlorhexidine solution. This procedure is performed twice a day. In between, suction whenever needed and cleansing with swabs soaked with carbonated bottled water is

performed
B The study group will be attended in the same manor but the swabs used for cleansing are soaked with carbonated water directly from freshly opened bottles. As the final part of the procedure oral mucosal surfaces are pencilled with a suspension of the probiotic bacterium Lactobacillus plantarum 299
Cultures from the oropharynx and tracheal secretions are taken at inclusion (day 1) and then on days 2,3,5,7,10,14 and 21 or before extubation if this occurs on a non-culture day

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lactobacillus plantarum and chlorhexidine

Primary outcome measure
Cultures from the oropharynx and tracheal secretions are taken at inclusion (day 1) and then on days 2, 3, 5, 7, 10, 14 and 21 or before extubation if this occurs on a non-culture day (The primary outcomes are validated for the part of the ICU stay during which the patient is intubated). The results of the cultures are used to assess the following:
1. To compare the number of cultures with pathogenic bacteria and fungi from oropharynx and tracheal secretions and the spectra of these microbiologic species
2. Recovery of Lactobacillus plantarum 299 in the treatment group as an indicator of aspiration

Secondary outcome measures
The following will be assessed during the ICU stay during which the patient is intubated:
1. Sequential Organ Failure Assessment (SOFA) score and Lung Injury Severity Score (LISS) will be measured daily during the ICU stay
2. Incidence of ventilator associated pneumonia during the ICU stay
3. Validation of microbiological findings compared to the use of antibiotics, monitored during the ICU stay
4. Infectious parameters (C-Reactive Protein [CRP] and White Blood Cell counts [WBC]), monitored daily during the ICU stay

For the whole ICU period:
5. ICU mortality

For the post-extubation period:
6. In-hospital mortality

Follow-up for survival will be carried out for 6 months from admission to the ICU.

Overall study start date
10/01/2004

Completion date
15/12/2007

Eligibility

Key inclusion criteria
1. 18 years or older
2. Critically ill patients anticipated to require mechanical ventilation for at least 24 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
50

Key exclusion criteria
1. Diagnosed with pneumonia at admission
2. Fractures on the facial skeleton or the skull base
3. Known ulcers in the oral cavity
4. Carrier of HIV or hepatitis
5. Moribund

Date of first enrolment
10/01/2004

Date of final enrolment
15/12/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Anaesthesiology and Intensive Care
Lund
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Sponsor information

Organisation
Probi AB (Sweden)

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Sponsor type
Industry

Website
http://www.probi.com/

ROR
https://ror.org/03yf63872

Funder(s)

Funder type
Industry

Funder Name
Probi AB (Sweden)

Funder Name
Region Skane (Regional public body responsible for health, medical and dental services)(Sweden)

Funder Name
The Scandinavian Society for Antimicrobial Chemotherapy Foundation

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	expanded study results	28/10/2018	31/12/2020	Yes	No
Results article	pilot study results	01/12/2008	31/12/2020	Yes	No