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The effect of probiotic therapy on nosocomial infections in the critically ill

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2017	Infections and Infestations	[_] Record updated 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0192133923

Study information

Scientific Title
The effect of probiotic therapy on nosocomial infections in the critically ill

Study objectives
Does early enteral feeding with probiotics reduce the rate of nosocomial (hospital acquired) infections in the critically ill?

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Infections and Infestations: Nosocomial infections

Interventions
1. Lactobacillus
2. Placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Probiotics

Primary outcome measure

Oropharyngeal nosocomial bacterial carriage rates, nosocomial infection rates, death rates, diarrhoea rates.

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/10/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
07/10/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Anaesthesia and Intensive Care
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nottingham University 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