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Use of probiotic yoghurt to prevent diarrhoea in critical care: A randomised double-blind, placebo-controlled trial

Submission date 12/05/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/05/2010	**Overall study status** Stopped	
Last Edited 30/08/2016	**Condition category** Digestive System	

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
7425

Study information

Scientific Title
Use of probiotic yoghurt to prevent diarrhoea in critical care: A randomised double-blind, placebo-controlled trial

Study objectives
Do probiotics reduce the incidence of diarrhoea in critically ill patients taking antibiotics?

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC, ref: 08/H1003/95

Study design
Single-centre randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Public Health Research

Interventions
Patients will be randomised to receive either one sachet of VSL#3 or placebo twice daily via their nasogastric tube, or feeding gastrostomy/jejunostomy. Probiotic/placebo administration will continue for the duration of antibiotic therapy and for a further 7 days following cessation of antibiotics.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Diarrhoea: defined as more than 3 loose stools per day (Bristol stool chart grade 7)

Secondary outcome measures
Clostridium difficile associated disease: Clostridium difficile A or B toxin (CDT) positive stool sample

Overall study start date
01/10/2008

Completion date
01/10/2010

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

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
Planned sample size: 192

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aintree University Hospitals
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Aintree University Hospitals NHS Foundation Trust (UK)

Sponsor details
Fazakerley Hospital
Lower Lane
Liverpool
England
United Kingdom
L9 7AL

Sponsor type
Hospital/treatment centre

Website
http://www.aintreehospitals.nhs.uk

ROR
https://ror.org/02h67vt10

Funder(s)

Funder type
Charity

Funder Name
Hospital Infection Society (UK)

Funder Name
National Institute of Academic Anaesthesia (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