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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
Dr Lindsay Parker

Contact details
Aintree University Hospitals
Fazakerley Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
Clostridium difficile associated disease: Clostridium difficile A or B toxin (CDT) positive stool sample

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Aintree University Hospitals NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration