

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
Registration date 12/05/2010	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 30/08/2016	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Single-centre randomised interventional prevention trial

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