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

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

**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

### 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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |