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# Probiotics for the prevention of antibiotic-associated diarrhoea and Clostridium difficile associated diarrhoea

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| **Submission date**<br>21/10/2010 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>21/10/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>01/11/2013 | **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

**Clinical Trials Information System (CTIS)**
2008-005244-16

**ClinicalTrials.gov (NCT)**
NCT00973908

**Protocol serial number**
8157

# Study information

## Scientific Title
Probiotics for the prevention of antibiotic associated diarrhoea and Clostridium difficile associated diarrhoea: a multicentre randomised interventional phase II prevention trial

## Study objectives
The study aims to establish whether VSL#3 compared to placebo prevents antibiotic-associated diarrhoea and Clostridium difficile associated diarrhoea in hospitalised patients on systemic antibiotics.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
North Staffordshire Local Research Ethics Committee 3 approved on the 22nd April 2010 (ref: 08 /H1201/147)

## Study design
Multicentre randomised interventional phase II prevention trial

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Gastrointestinal

## Interventions
Intervention: 1 sachet of VSL#3 twice daily for the duration of the antibiotic course and seven days thereafter.
Control: 1 sachet of placebo twice daily for the duration of the antibiotic cource and seven days thereafter.

Follow-up until 28 days after the last antibiotic dose.
Study entry: single randomisation only

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
VSL#3

### Primary outcome(s)
Development of CDAD, measured at 28 days after last antibiotic dose

### Key secondary outcome(s))
1. 30 day mortality
2. Development of AAD, measured at 28 days post-last antibiotic dose
3. Length of hospital stay

### Completion date
10/03/2011

## Eligibility

### Key inclusion criteria
1. Systemic antibiotics
2. Aged 18 years or older, either sex
3. Able to take enteral medication (sachets)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Diarrhoea at screening
2. Unable to take enteral medication
3. Patients on intensive care units
4. Severe immunosuppression (neutropenia, acquired immunodeficiency syndrome [AIDS], congenital immunoparesis, chemotherapy)
5. Risk of endocarditis (artificial heart valves, history of rheumatic heart disease or infective endocarditis)
6. Regular consumption of probiotics until 1 week prior to admission
7. Acute severe pancreatitis
8. Persistent vomiting (two days or more)

### Date of first enrolment
01/04/2010

### Date of final enrolment
10/03/2011

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Wrightington, Wigan and Leigh NHS Foundation Trust**
Wigan
United Kingdom
WN1 2NN

# Sponsor information

### Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust (UK)

### ROR
https://ror.org/028mrxf52

# Funder(s)

### Funder type
Industry

### Funder Name
Ferring Pharmaceuticals Ltd (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? |
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| Results article | results | 01/06/2013 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |