

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

<b>Submission date</b> 21/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/11/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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 course 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/028mrx52>

## 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