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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-005244-16

IRAS number

ClinicalTrials.gov number
NCT00973908

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Development of CDAD, measured at 28 days after last antibiotic dose

Secondary outcome measures
1. 30 day mortality
2. Development of AAD, measured at 28 days post-last antibiotic dose
3. Length of hospital stay

Overall study start date
01/04/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 445; UK sample size: 445

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
England

United Kingdom

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)

Sponsor details
Clinical Trials Unit
Hall Lane
Appley Bridge
Wigan
England
United Kingdom
WN6 9EP

Sponsor type

Hospital/treatment centre

Website
http://www.wiganleigh.nhs.uk

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Industry

Funder Name
Ferring Pharmaceuticals Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/06/2013		Yes	No