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Clostridium difficile - adjuvant therapy with high dose VSL#3® will shorten hospital stay and reduce relapse rates in Clostridium difficile associated diarrhoea

Submission date 20/12/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/02/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/06/2016	**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
07/H0105/71

Study information

Scientific Title

Clostridium difficile - adjuvant therapy with high dose VSL#3® will shorten hospital stay and reduce relapse rates in Clostridium difficile associated diarrhoea: a multicentre double blind randomised placebo controlled trial

Study objectives
The aim of this proposed study is to assess whether high dose VSL#3® (a combined probiotic food supplement) can reduce length of symptoms and length of stay on a Clostridium difficile cohort ward in a district general hospital. The study will also assess any effect of VSL#3® on the incidence of colitis diagnosed in this cohort of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the London Research Ethics Committee (REC) as of 08/01/2009.

Study design
Double-blind randomised placebo-controlled multi-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Clostridium difficile associated diarrhoea

Interventions
Adjuvant VSL#3® (probiotic) or placebo, two sachets three times per day, one hour prior to antibiotic therapy.

Total duration of treatment is dependent on the length of symptoms. These usually range from 7 - 14 days but can be longer. Full dose (2 sachets three times a day [tds]) of VSL#3 (probiotic) will be continued until patient is symptom free for 48 hours and then a reduced dose of 2 sachets daily for two weeks following discharge. Therefore the average length of treatment will be one month. Patients will be followed up 4 weeks after resolution of their symptoms to see whether there has been a recurrence.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)

1. Reduction in length of symptoms by 20%, approx expectation is 7 - 10 days
2. Reduction in rates of recurrence of Clostridium difficile associated diarrhoea (CDAD) by 50%, measured within 4 weeks of resolution of symptoms

Key secondary outcome(s))
1. Reduction in mortality due to primary endpoints mentioned above, measured from admission to one month post resolution of symptoms
2. Reduction in incidence of colitis (colitis diagnosed by abdominal x-ray or computed tomography [CT] and serological markers +/- sigmoidoscopy)

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Any consenting adult patient over the age of 18 years admitted to a Clostridium difficile Cohort Ward in either Gloucester Royal Hospital or Cheltenham General Hospital. Male and female genders will be included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
There is no upper age limit and patients with IBD will not be excluded. Apart from this, the following patients will be excluded:
1. Those with evidence of dilated colon on plain abdominal film on admission
2. Any patient known to be immunosuppressed (including those on steroids)
3. Any patient refusing the VSL#3® as part of their treatment regime
4. Patients with lactose intolerance or allergy
5. Any patient with a history of rheumatic heart disease or prosthetic heart valve
6. Any patient with a history of endocarditis

Date of first enrolment
01/06/2009

Date of final enrolment

01/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
37 Shirehampton Road
Bristol
United Kingdom
BS9 1BL

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK) - researchers are receiving no financial renumeration for the work on this project

Funder Name
Ferring Pharmaceuticals Ltd (UK) - supplying the VSL#3® and placebo free of charge

Funder Name
Added 15/09/2008:

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) - pending

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration