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

	[X] Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Digestive System	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Alexandra di Mambro

Contact details

37 Shirehampton Road Stoke Bishop Bristol United Kingdom BS9 1BL

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

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes