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A double blind, randomised, placebo controlled trial investigating the efficacy and role of Synbiotic Cocktail 2000 in the treatment of Clostridium difficile diarrhoea and colitis

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
17/04/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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
N0265122366

Study information

Scientific Title

A double blind, randomised, placebo controlled trial investigating the efficacy and role of Synbiotic Cocktail 2000 in the treatment of Clostridium difficile diarrhoea and colitis

Study objectives
1. To assess the role of Synbiotic Cocktail 2000 on symptom duration and relapse rates in patients with one or more episodes of C. difficile diarrhoea
2. To confirm the safety, tolerance and efficacy of Synbiotic Cocktail 2000 used with metronidazole for treatment of C. difficile diarrhoea and colitis compared with metronidazole and placebo
3. To assess the rate of C. difficile toxin and C. difficile elimination with Synbiotic Cocktail 2000 when compared to placebo
4. To investigate the ability of Synbiotic Cocktail 2000 to inhibit C. difficile and Toxin A production in vitro
5. To investigate the efficacy and duration of human gut colonisation by Synbiotic Cocktail 2000 during and after treatment
6. To investigate and characterise mucosa-associated bacteria in patients with antibiotic associated colitis before and after treatment with Synbiotic Cocktail 2000

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Clostridium difficile diarrhoea and colitis

Interventions
Treatment will be initiated at the time of acute relapse and patients will commence on oral metronidazole with either probiotic or placebo. Antibiotic therapy will be continued for seven days while probiotic or placebo will continue for three weeks. Any relapse in symptoms will require oral vancomycin. Stool samples will be obtained daily during initial metronidazole therapy until two stool samples are negative for C. difficile toxin. Daily stool diaries will be kept by all patients. At the end of the three week period of probiotic therapy, patients will undergo a rigid sigmoidoscopy examination and one rectosigmoid biopsy obtained for culture.

Intervention Type
Other

Primary outcome(s)
Disease relapse over one month

Key secondary outcome(s))
1. Disease relapse over three months
2. Rate of loss of C. difficile and toxin from the stool
3. Time to resolution of diarrhoea

Completion date
16/01/2004

Eligibility

Key inclusion criteria
Any patient with a stool sample positive for Toxin A and clinically symptomatic in the Trust will be offered entry into the trial.

ASSESSMENT ON ADMISSION INTO TRIAL:
1. History and physical examination
2. Blood tests
3. Stool analysis for C. difficile and Toxin A
4. Rigid or flexible sigmoidoscopy with biopsies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Patients may be removed from the study if one or more of the following occurs:
1. Protocol violation or non-compliance on part of the patient
2. Refusal of the patient to continue treatment and a decision by the investigator that termination is in the patient's best medical interest (or a significant unrelated medical illness or complication)

Date of first enrolment
16/01/2003

Date of final enrolment
16/01/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration