

# 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

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|----------------------------------------|----------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>12/09/2003   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>12/09/2003 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>17/04/2015       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                          | <input type="checkbox"/> Results                     |
|                                        |                                                          | <input type="checkbox"/> Individual participant data |
|                                        |                                                          | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr S Pathmakanthan

### Contact details

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Selly Oak Hospital  
Birmingham  
United Kingdom  
B29 6JD

## 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

### **Primary study design**

Interventional

### **Study design**

Double-blind randomised placebo-controlled trial

### **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