The FECAL trial, Fecal therapy to Eliminate Clostridium difficile Associated Longstanding diarrhoea.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25892

Source
NTR

Brief title
the FECAL trial

Health condition

1. Clostridium difficile;

2. Recurrent (NLD: recidiverend);

3. antibiotic associated diarrhoea;

4. diarrhoea (NLD: diarree);

5. feces (NLD: ontlasting);

6. transplantation (NLD: transplantatie).

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
the Netherlands
Source(s) of monetary or material Support: ZonMW

Academic Medical Center Amsterdam

Intervention

Outcome measures

Primary outcome

Diarrhoea and Clostridium difficile toxin in stool after 10 weeks.

Secondary outcome

1. Diarrhoea and Clostridium difficile toxin in stool after five weeks;

2. Costs;

3. Quality of life;

4. Inflammatory markers.

Study description

Background summary

Recurrent Clostridium difficile associated diarrhoea is an emerging problem in Hospitals and Nursing Homes throughout the western world. Clostridium difficile associated diarrhoea is thought to recur due to persisting spores and bacteria in the intestine on the one hand, and a long term disturbance of intestinal homeostasis on the other. Restoring the intestinal flora with feces from a healthy donor is believed to be effective in the prevention of recurrences. This trial is performed in which infusion of donor feces through a duodenal tube is compared with conventional antibiotic therapy, or antibiotic therapy with bowel lavage.

Endpoints are diarrhoea and Clostridium toxin in stool after 10 weeks (primary) and after 5 weeks, as well as inflammatory markers, cost and quality of life. Follow up is 10 weeks.

Study objective

Hypothesis: An important factor in recurrence of Clostridium difficile associated diarrhoea is persistent disturbance of intestinal flora. With restoration of flora by feces from a healthy donor future recurrences can be prevented.

Study design

Day 1, 5, 7, 14, 21, 28, 35, 42, 49, 56, 63, 70.

Intervention

Arm 1: vancomycin 500 mg qid, 14 days;

Arm 2: vancomycin 500 mg qid, 14 days, with a bowel lavage with kleanprep on the fourth day;

Arm 3: vancomycin 500 mg qid 4 days, followed by a bowel lavage, followed by infusion of donor feces through a nasoduodenal tube on the fifth day.

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Eligibility criteria

Inclusion criteria

1. Patient 18 years or older;

2. proven recurrence of Clostridium difficile associated diarrhoea (positive toxin test and diarrhoea defined as more than 3 loose or watery stools per day or >8 in 48 hours);

3. In previous episodes of Clostridium difficile associated diarrhoea at least one proper course of antibiotic therapy. (at least vancomycin 125 mg qid for 10 days or metronidazole 500 mg tid for 10 days).

Exclusion criteria

1. Pregnancy;

2. life expectancy of less than three months;

3. expected longlasting immunecompromised state (CD4<240, cytotoxic chemotherapy);

4. Prednisolon (>20 mg a day) expected to be prescibed for more than 30 days;

5. Need for continuous use of antibiotic other than for treatment of Clostridium difficile infection.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1135
NTR-old	NTR1177
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A