

Hookworm infestation as therapy in Crohn's disease

Submission date 12/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/07/2017	Condition category Digestive System	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.2, 23 March 2006

Study information

Scientific Title

Hookworm infestation as therapy in Crohn's disease

Study objectives

Does a single dose of hookworm larvae reduce disease activity in Crohn's Disease (CD) (as measured by the Crohn's Disease Activity Index [CDAI], biochemical markers of severity) compared to placebo?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Research Ethics Committee, 07/11/2005, ref: 05/Q2403/144

Study design

Multicentre randomised double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Crohn's disease

Interventions

A dose of ten L3 larvae of *Nicrophorus americanus* pipetted in solution onto a gauze pad and administered onto the skin under sticking plaster. The placebo will consist of 2 µM of standard histamine solution, as used in skin prick testing, applied topically to the skin under a sealed dressing. This produces an itch lasting for approximately ten seconds.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in the CDAI at week 12

Secondary outcome measures

1. Disease activity, measured by the Harvey Bradshaw Index (HBI)
2. Inflammatory markers (Erythrocyte Sedimentation Rate [ESR], C-Reactive Protein [CRP]), platelet count
3. Circulating Interleukin 2 (IL2) receptor and Interleukin 6 (IL6) levels (measured by Elisa) used as an index of efficacy as well as of a switch between Th1 and Th2 (T-Helper cells) responsiveness
4. Patients' global impression of change
5. Cytokine profiles (IL2, Interleukin 4 [IL4], Interleukin 5 [IL5], Interleukin 10 [IL10], Transforming Growth Factor beta [TGF beta]) and gamma interferon from peripheral blood mononuclear cells measured by Elisa and measured conjunction to show evidence of a Th1/Th2 switch, and change in the Treg and Tr1 phenotype
6. Quality of life, measured using the Inflammatory Bowel Disease Questionnaire (IBDQ)
7. Health status, measured using the EQ-5D

Overall study start date

01/02/2006

Completion date

31/01/2008

Eligibility**Key inclusion criteria**

1. Diagnosis of moderately active Crohn's disease (CDAI between 220 and 450) requiring outpatient treatment
2. Clinically acceptable baseline screening tests
3. Aged between 18 and 80
4. Have given written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

56

Key exclusion criteria

1. Positive stool culture for enteric pathogens or Clostridium difficile
2. Bowel perforation, or obstructive symptoms not due substantially to active inflammation

3. Patients whose diarrhoea is believed to be due to short bowel syndrome or bile salt malabsorption (making the CDAI invalid)
4. Female patients of child bearing potential who are not willing or able to use at least one highly effective contraceptive method throughout the study. In the context of this study, an effective method is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly such as: implants, injectables, combined oral contraceptives, sexual abstinence or vasectomised partner
5. Concomitant immunosuppressive therapy (cyclosporin in the last three months, methotrexate in the last six months, prednisolone more than 10 mg/day) or infliximab in the past three months. Azathioprine is permitted if the patient has been on a stable dose for at least two months
6. Serious intercurrent infection or other active disease up to three months prior to treatment
7. Known Human Immunodeficiency Virus infection

Date of first enrolment

01/02/2006

Date of final enrolment

31/01/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nottingham University Hospital

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research and Commercialisation Office

Kings Meadow Campus

Lenton Lane

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England

United Kingdom

NG7 2NR

Sponsor type

University/education

Website

<http://www.nottingham.ac.uk>

ROR

<https://ror.org/01ee9ar58>

Funder(s)**Funder type**

Charity

Funder Name

The Eli and Edythe L. Broad Foundation (reference number: BMRP proposal No. IBD-0184)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration