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Hookworm infestation as therapy in Crohn's disease

Submission date	Recruitment status	[ ] Prospectively registered
12/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/07/2017	Digestive System	[ ] 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
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

Study type(s)
Treatment

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(s)
Change in the CDAI at week 12

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 vastectomised 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 Immunodieficiency Virus infection

Date of first enrolment
01/02/2006

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (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

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	11/11/2025	No	Yes