

Epidermal growth factor enema versus mesalazine enema for the treatment of mild-to-moderate active left-sided ulcerative colitis

Submission date 24/08/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/07/2017	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

Protocol serial number
N/A

Study information

Scientific Title

Epidermal growth factor enema versus mesalazine enema for the treatment of mild-to-moderate active left-sided ulcerative colitis

Study objectives

Epidermal Growth Factor (EGF) is as effective as mesalazine in the treatment of mild-to-moderately active left-sided Ulcerative Colitis (UC).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1 – approval pending

Study design

Interventional randomised double-blind case-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Left-sided ulcerative colitis

Interventions

Group 1: Patients will receive a two week course of EGF enema

Group 2: Patients will receive a two week course of mesalazine enema

Participants will be randomly assigned into either group and all parties involved will be blinded until the end of the follow-up period.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Epidermal growth factor, mesalazine

Primary outcome(s)

Remission at week two as determined by a UC-DAI score of less than two

Key secondary outcome(s))

1. Remission at week four as determined by a UC-DAI score of less than two
2. Improvements in UC-DAI score by more than two points from baseline at week two and week four
3. Improvements in Histological-DAI score by more than two points from baseline at week two and week four

Completion date

30/09/2008

Eligibility

Key inclusion criteria

1. Males and females aged above 18 with a definite diagnosis of UC or proctitis
2. Mild-to-moderate disease activity with a UC Disease Activity Index (UC-DAI) score between three and eight

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with infectious colitis
2. Colonic inflammation extending proximal to the left colon (i.e. beyond the splenic flexure on sigmoidoscopic examination)
3. Patients receiving oral maintenance therapy with a total daily dose of more than 3 g of mesalazine within 30 days prior to study entry
4. Use of any immunosuppressive agent within 90 days prior to the study
5. Intake of corticosteroids (orally or rectally) within seven days prior to entry
6. Chronic use of non-steroidal anti-inflammatory drugs in seven days prior to inclusion (chronic use defined as drug intake for a minimum of seven consecutive days)
7. Presence of severe renal/hepatic impairment, malignant disease and allergies to salicylates

Date of first enrolment

01/10/2006

Date of final enrolment

30/09/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Leicester Royal Infirmary
Leicester
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LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
<https://ror.org/02fha3693>

Funder(s)

Funder type
Research organisation

Funder Name
Broad Medical Research Program, the Eli and Edythe L. Broad Foundation (IBD-0172R)

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