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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/09/2006	**Overall study status** Completed	
Last Edited 11/07/2017	**Condition category** Digestive System	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Secondary outcome measures
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

Overall study start date
01/10/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

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Trust Headquarters
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Sponsor type
Hospital/treatment centre

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

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