

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

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