# Zinc sulphate enema for the management of non-infectious mild to moderate distal colitis

Submission date	Recruitment status	☐ Prospectively registered
12/09/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
15/11/2011	Digestive System	Record updated in last year
15/11/2011	• •	Record updated in last ye

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mr AM El-Tawil

#### Contact details

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# Additional identifiers

Protocol serial number N0064109021

# Study information

Scientific Title

**Study objectives** 

To examine the effect of zinc sulphate solution enema on patients with mild to moderate distal colitis. Although it is appreciated that Crohn's disease and ulcerative colitis result in malabsorption of a variety of nutrients and that hypozincemia may occur in patients with Crohn's disease or ulcerative colitis, relatively little investigation has been directed toward the sequel of zinc deficiency in this disorder. We assume that zinc has an anti-inflammatory power. If this approach proves effective then it is likely to alleviate much suffering.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Colitis

#### **Interventions**

Single centre, patient volunteers, prospective, controlled, therapeutic, observational, double-blind, placebo, drugs, invasive procedures, randomised.

FUNDING NOT SECURED AND TRIAL NOT STARTED AS OF APRIL 2005.

### Intervention Type

Other

#### Phase

Not Applicable

### Primary outcome(s)

Not provided at time of registration

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

01/04/2003

# **Eligibility**

### Key inclusion criteria

60 patients.

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

### Age group

**Not Specified** 

#### Sex

**Not Specified** 

### Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

01/04/2002

### Date of final enrolment

01/04/2003

# Locations

# Countries of recruitment

United Kingdom

England

# Study participating centre

Department of Gastroenterology

Birmingham United Kingdom B18 7QH

# Sponsor information

# Organisation

Department of Health (UK)

# Funder(s)

# Funder type

Government

### Funder Name

Sandwell and West Birmingham Hospitals NHS Trust - City Hospital (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration