

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

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