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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 15/11/2011	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
01/04/2003

Eligibility

Key inclusion criteria
60 patients.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
Department of Gastroenterology
Birmingham

United Kingdom
B18 7QH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

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

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