ISRCTN87269559 https://doi.org/10.1186/ISRCTN87269559

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

Contact name
Mr AM El-Tawil

Contact details
Department of Gastroenterology
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH
+44 (0)121 554 3801

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

Primary study design
Interventional

Study design
Randomised controlled trial

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