ISRCTN97214617 https://doi.org/10.1186/ISRCTN97214617

Constipation in Distal Ulcerative Colitis: A clinico-radiological comparison of the effectiveness of fibre supplementation vs polyethylene glycol laxative

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
08/04/2014

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S L Bloom

Contact details
Gastroenterology
G.I. Unit, 2nd Floor
The Middlesex Hospital
Mortimer Street
London
United Kingdom
W1N 8AA
+44 (0)20 7380 9126

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0263128752

Study information

Scientific Title

Study objectives
To determine whether polyethylene glycol laxative is superior to fibre supplementation in relieving constipation and improving colonic transit in patients with distal ulcerative colitis

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Digestive System: Ulcerative colitis

Interventions
1. Fibre supplementation
2. Polyethylene glycol laxative

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)

fibre supplementation vs polyethylene glycol laxative

Primary outcome measure
Assessment of improvement in colonic transit by radioopaque markers study at the end of 4 weeks of treatment

Secondary outcome measures
Not provided at time of registration

Overall study start date
12/08/2003

Completion date
01/12/2006

Eligibility

Key inclusion criteria
146 patients from Gastroenterology

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
146

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
12/08/2003

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gastroenterology
London
United Kingdom
W1N 8AA

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Trust (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