

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/04/2014	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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