

Dietary fibre supplementation to prevent ulcerative colitis relapse: randomised double-blind placebo controlled clinical trial

Submission date 04/02/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/03/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/03/2008	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

v.13

Study information

Scientific Title

Study objectives

By taking 60 g of oat bran daily the relapse rate of patients with ulcerative colitis will be lowered from 40% to 20% at six months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the ethics committee of Linköping University, Sweden (ref: M 159-04)

Primary study design

Interventional

Study design

Randomised double-blind placebo controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Ulcerative colitis and proctitis in remission

Interventions

60 g of oat bran to the daily diet for six months versus no intervention.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oat bran

Primary outcome(s)

Colitis relapse at six months.

Key secondary outcome(s)

The following will be assessed at six months:

1. General health
2. Bowel symptoms
3. Faecal butyrate concentration

Completion date

20/07/2009

Eligibility**Key inclusion criteria**

1. Adults with ulcerative colitis or proctitis in clinical and endoscopic remission following a colitis relapse within prior 12 months
2. Written consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Antibiotics at inclusion
2. Steroids in last two weeks
3. Ongoing treatment with immunosuppressive drugs
4. Pregnancy or planned pregnancy
5. Concomitant serious disorder
6. Inability to comply with study protocol

Date of first enrolment

15/10/2006

Date of final enrolment

20/07/2009

Locations**Countries of recruitment**

Sweden

Study participating centre

Norrköping Hospital NSÖ stab

Norrköping

Sweden

S-60182

Sponsor information**Organisation**

Lantmännen Food (Sweden)

Funder(s)

Funder type

Industry

Funder Name

Lantmannen Food R&D (Sweden)

Funder Name

Medical Research Council of South-East Sweden (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration