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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/03/2008	**Overall study status** Completed	
Last Edited 20/03/2008	**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
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)

Study design
Randomised double-blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (only in Swedish)

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 measure
Colitis relapse at six months.

Secondary outcome measures
The following will be assessed at six months:
1. General health
2. Bowel symptoms
3. Faecal butyrate concentration

Overall study start date
15/10/2006

Completion date
20/07/2009

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
130

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)

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Sponsor type
Industry

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

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