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Fibre supplementation in addition to loperamide for faecal incontinence in adults: a randomised trial

Submission date	Recruitment status	[_] Prospectively registered
23/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2008	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
OEC 01/07/055

Study information

Scientific Title

Study objectives
To evaluate the efficacy of fibre supplementation and loperamide in comparison to a low-residue diet and lopermide in the conservative treatment of faecal incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Otago Ethics Committee on the 30th July 2001.

Study design
Double-blind randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Faecal incontinence

Interventions
All patients received loperamide. Most patients were advised to start by taking one tablet (2 mg) twice a day. Patients with a tendency to constipation were advised to start on one tablet daily. All patients were given both verbal instruction and an advice sheet about using loperamide which advised titrating the loperamide dose to firm stool but to avoid constipation. Glycerine suppositories were supplied for use in the event of troublesome constipation.

Patients were randomised to either combination treatment A or B for six weeks, crossed-over and re-evaluated after a further six weeks. It was assumed that it would take a week or two for the patients to adjust to the new treatment after cross over, and they were advised of this. They

were asked to fill out the outcome questionnaires in relation to previous 4 weeks of the 6 weeks treatment period in each arm of the study. Both participants and clinicians/researchers were blinded.

Treatment A:
This consisted of:
1. An untitled dietary advice sheet for a balanced low residue diet
2. Placebo supplement (Karicare infant food thickener - light cream colored course powder containing pregelatinised maize starch, maltodextrin, locust bean gum) to be taken as one rounded teaspoon mixed in a glass of water at breakfast and dinner
3. Loperamide (taken as described above)

Treatment B:
This consisted of:
1. An untitled dietary advice sheet for a balanced diet consisting of both high and low residue items
2. Fibre supplement (psyllium hydrophilic mucilloid) to be taken as one rounded teaspoon with a glass of water at breakfast and dinner
3. Loperamide (taken as described above)

The dietary advice sheets were developed in consultation with the hospital Nutrition department. An important consideration in designing the dietary advice sheets was producing advice that would optimise compliance for a long term change, while encouraging healthy eating.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Loperamide, psyllium hydrophilic mucilloid

Primary outcome measure
Faecal Incontinence Severity Index (FISI) patient-weighted score, measured at baseline, 6 weeks at cross over and at 12 weeks at conclusion of the second treatment period.

Secondary outcome measures
1. 36-item Short Form health survey (SF-36)
2. Faecal Incontinence Quality of Life scale (FIQL)

All questionnaires were performed at baseline, 6 weeks at cross over and at 12 weeks at conclusion of the second treatment period.

Overall study start date
01/12/2001

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. Over eighteen years of age
2. Referred to an outpatient colorectal service with the primary presenting problem of chronic incontinence to mucus, liquid and/or solid stool
3. Living independently
4. Able to read and complete the study information and questionnaires

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Full thickness rectal prolapse
2. Inflammatory bowel disease
3. Other pathologies requiring surgery
4. Diabetes (chosen supplement contraindicated)
5. Previous treatment for faecal incontinence

Date of first enrolment
01/12/2001

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
New Zealand

Study participating centre
Department of Medical and Surgical Sciences
Dunedin
New Zealand
9054

Sponsor information

Organisation
University of Otago (New Zealand)

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Sponsor type
University/education

Website
http://www.otago.ac.nz/

ROR
https://ror.org/01jmxt844

Funder(s)

Funder type
University/education

Funder Name
University of Otago (New Zealand) - Research Grant

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2008		Yes	No