

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

Submission date 23/10/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/11/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/06/2008	Condition category Digestive System	☐ Individual participant data

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
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 loperamide 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.

Primary study design

Interventional

Study design

Double-blind randomised cross-over trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/01jmxt844>

Funder(s)**Funder type**

University/education

Funder Name

University of Otago (New Zealand) - Research Grant

Results and Publications

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