

A randomised controlled trial of biofeedback versus laxatives for chronic idiopathic constipation in women

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/09/2013	Condition category Digestive System	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0515088411

Study information

Scientific Title

Study objectives

Biofeedback therapy leads to improved gut function and improved well being and is superior to standard laxative treatment.

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: Constipation

Interventions

Group 1: Single patients 60 min session involving a detailed history of the patient. Advice given on diet and defaecatory posture. Gut function explained and defaecatory exercises demonstrated using balloon expulsion. Patients will practice exercises at home. Laxatives stopped. Followed up at 16 weeks.

Group 2: The same assessment as Group 1 with the same advice and information. Four subsequent 30-40 min sessions at 4 weekly intervals with the same Biofeedback Nurse to practice balloon expulsion and reinforce information.

Group 3: The same assessment as Group 1 with the same advice on diet, etc, but no information on gut function or defaecatory dynamics and no Biofeedback exercises.

Patients will be commenced on Bisacodyl 1-2 at night increasing up to 3 at night if required. In addition they will be allowed to use suppositories as required. Four subsequent 30-40 min sessions at 4 weekly intervals with the same Biofeedback Nurse to discuss laxative titration and reinforce information and advice.

All patients will be assessed at 4 and 12 months after commencing treatment.

Patients from Groups 1 and 3 can cross over to Group 2 if they are not satisfied with the outcome at 4 months after commencing treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

biofeedback versus laxatives

Primary outcome measure

Diaries, questionnaires, abdominal transit study.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2000

Completion date

30/06/2003

Eligibility

Key inclusion criteria

150 patients with 50 patients in each group, from age 18 years.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

150

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/2000

Date of final enrolment

30/06/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Department of Physiology**

Harrow, Middlesex

United Kingdom

HA1 3UJ

Sponsor information**Organisation**

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

North West 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