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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 24/09/2013	**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

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
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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