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A phase III, multicentre, single blind, randomised controlled trial in the use of hyperbaric oxygen therapy versus biofeedback therapy in patients with chronic faecal incontinence associated with pudendal neuropathy

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 27/09/2016	**Condition category** Signs and Symptoms	

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
N0084122586

Study information

Scientific Title
A phase III, multicentre, single blind, randomised controlled trial in the use of hyperbaric oxygen therapy versus biofeedback therapy in patients with chronic faecal incontinence associated with pudendal neuropathy

Study objectives
To determine and compare the effects of hyperbaric oxygen therapy versus biofeedback on incontinence severity, Quality of Life, anorectal neurophysiology and daily episodes.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Faecal incontinence

Interventions
A) hyperbaric oxygen therapy versus B) biofeedback.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/01/2003

Completion date
01/06/2005

Eligibility

Key inclusion criteria
100 patients, 50 on each arm.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50 patients in each arm

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
22/01/2003

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Surgical Unit
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ

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
Research organisation

Funder Name
The North and South Bank Research and Development Consortium

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