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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

Contact name
Mr R Mathew

Contact details
Academic Surgical Unit
Castle Hill
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ
+44 (0)1482 875 875
r.mathew@hull.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/06/2005

Eligibility

Key inclusion criteria
100 patients, 50 on each arm.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Research organisation

Funder Name
The North and South Bank Research and Development Consortium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration