

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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
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

Study design

Randomised controlled trial

Primary study design

Interventional

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