

Transcutaneous magnetic cortical stimulation (TMS) for assessment of the external anal sphincter in neurogenic faecal incontinence

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 29/07/2008	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr ES Kiff

Contact details

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Additional identifiers

Protocol serial number

N0226118468

Study information

Scientific Title

Study objectives

1. How do treatments for faecal incontinence have effect?
2. Does biofeedback have a neuroplastic cortical effect in patients with faecal incontinence?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised, single-blinded, controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nervous System Diseases: Neurogenic faecal incontinence

Interventions

Patients randomised to 1 of 3 groups, all will receive current biofeedback therapy, but at different time intervals:

1. Group 1 - Behaviour Modification - Baseline TMS - Behaviour Modification - TMS - Biofeedback - TMS
2. Group 2 - Biofeedback - Baseline TMS - Biofeedback - TMS
3. Group 3 - (Control) - Baseline TMS - repeat TMS - Biofeedback - TMS

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To establish any cortical neuroplastic changes or nerve conduction changes in response to current treatments for faecal incontinence.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2004

Eligibility

Key inclusion criteria

30 Patients over the age of 18 with neurogenic faecal incontinence will be recruited from the referrals to Mr ES Kiff and 15 controls.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2002

Date of final enrolment

01/10/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of General Surgery

Manchester

United Kingdom

M23 9LT

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

South Manchester University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2005		Yes	No