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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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
29/07/2008

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised, single-blinded, 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
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 measure
To establish any cortical neuroplastic changes or nerve conduction changes in response to current treatments for faecal incontinence.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

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
England

United Kingdom

Study participating centre
Department of General Surgery
Manchester
United Kingdom
M23 9LT

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
South Manchester University 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

Study outputs

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