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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

**Registration date**
12/09/2003

**Last Edited**
29/07/2008

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**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 |