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Randomised controlled trial of anal electrical stimulation in adults with faecal incontinence

Submission date 27/11/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/11/2001	**Overall study status** Completed	
Last Edited 20/10/2010	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Christine Norton

Contact details
Physiology Unit
St Mark's Hospital
Watford Road
Harrow Middlesex
United Kingdom
HA1 3UJ
+44 (0)20 8235 4167
csnorton@aol.com

Additional identifiers

Protocol serial number
AP0894

Study information

Scientific Title

Study objectives
Anal electric stimulation, used on a daily basis at home for eight weeks, would improve symptoms of faecal incontinence and anal sphincter pressures when compared with "sham" electric stimulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Harrow Research Ethics Committee gave approval.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Faecal incontinence

Interventions
Patient self-rating of change, bowel diary, bowel symptom questionnaire, quality of life, anal manometry

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. One-week bowel diary
2. Symptom questionnaire
3. Manometry
4. Patients' evaluation of outcome

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/01/2005

Eligibility

Key inclusion criteria
Adults (aged greater than or equal to 18 years, either sex) with faecal incontinence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients refusing informed consent
2. Children under 18 years old
3. Pregnant females or those within six weeks of vaginal delivery
4. Patients with a history of pelvic malignancy
5. Patients with active inflammatory bowel disease
6. Patients with active perianal sepsis or painful haemorrhoids or fissure and patients with previous experience of using an electric stimulator to treat urinary or faecal incontinence

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Physiology Unit
Harrow Middlesex
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Action Medical Research (UK)

ROR
https://ror.org/01wcqa315

Funder(s)

Funder type
Not defined

Funder Name
Action Medical Research (UK)

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006		Yes	No