

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

Submission date 27/11/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/11/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/10/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.

Study design

Randomised controlled trial

Primary study design

Interventional

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