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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Christine Norton

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

90

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

England

United Kingdom

Study participating centre Physiology Unit

Harrow Middlesex United Kingdom HA1 3UJ

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House Horsham West Sussex United Kingdom RH12 2DP

Sponsor type

Charity

Website

http://www.action.org.uk/

ROR

https://ror.org/01wcqa315

Funder(s)

Funder type

Not defined

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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	01/02/2006		Yes	No