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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

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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