

An evaluation of pelvic floor muscle exercises and electrical muscle stimulation in patients with stress incontinence

Submission date
01/03/2001

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
01/03/2001

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
16/01/2009

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

AP0813

Study information

Scientific Title

An evaluation of pelvic floor muscle exercises and electrical muscle stimulation in patients with stress incontinence: a randomised, double-blind, controlled trial

Study objectives

To evaluate a new pattern of electrical of electrical stimulation as a treatment for stress incontinence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blind controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stress incontinence

Interventions

Women will be randomly allocated to one of the following groups:

1. Pelvic floor exercises alone
2. The new pattern of electrical stimulation alone
3. Pelvic floor exercises and the new pattern of electrical stimulation

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Patients were assessed pre, mid and post-treatment using:

1. Digital vaginal assessment of pelvic floor muscle strength using the modified Oxford Grading Scale
2. Assessment of vaginal muscle strength and endurance using the PRS 9300 perineometer (Incare Medical Products, USA)
3. One-hour pad test as recommended by the International Continence Society (ICS)

Key secondary outcome(s)

The following were only used pre- and post-treatment:

1. Seven-day frequency/volume chart
2. 36-item Short Form Health Survey (SF-36)

3. The Incontinence Impact Questionnaire
4. The Urogenital Distress Inventory

Completion date

31/12/2000

Eligibility

Key inclusion criteria

1. Females with stress incontinence between the ages of 18 and 70.

Added 12/01/2009:

2. Urodynamically proven stress incontinence
3. No neurological conditions diagnosed by consultant

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

Female

Key exclusion criteria

Added 12/01/2009:

1. Previous electrical stimulation for stress incontinence
2. Prolapse
3. Pregnancy
4. Pacemakers and cardiomyopathy
5. Abnormal urological/gynaecological findings
6. Urinary tract/vaginal infection
7. Recent pelvic floor surgery (within the last six months)

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Centre for Rehabilitation Science

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

Action Medical Research (UK)

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

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	01/12/2000		Yes	No