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

| Submission date   | <b>Recruitment status</b> No longer recruiting | Prospectively registered    |  |  |
|-------------------|--|-----------------------------|--|--|
| 01/03/2001        |  | ☐ Protocol                  |  |  |
| Registration date | Overall study status                           | Statistical analysis plan   |  |  |
| 01/03/2001        | Completed                                      | [X] Results                 |  |  |
| Last Edited       | Condition category                             | Individual participant data |  |  |
| 16/01/2009        | Urological and Genital Diseases                |                             |  |  |

# 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              |