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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

Registration date
01/03/2001

Overall study status
Completed

Last Edited
16/01/2009

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/01/2000

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Added 12/01/2009: 27

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
England

United Kingdom

Study participating centre
Centre for Rehabilitation Science
Manchester
United Kingdom
M13 9WL

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
Charity

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	01/12/2000		Yes	No