

Re-education of the pelvic floor in women with urinary stress incontinence

Submission date

30/09/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

30/09/2004

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

07/09/2015

Condition category

Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

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

M0001127331

Study information

Scientific Title

Re-education of the pelvic floor in women with urinary stress incontinence

Study objectives

One in four women suffer from Urinary Stress Incontinence (USI). The literature search suggests there is evidence from clinical experience and from research into the management of low back pain that retraining of the transversus abdominis muscle using real time ultrasound can facilitate correct tonic activity of the pelvic floor muscles (Richardson et al, 1999 and Critchely et al 2002). Studies so far of facilitation of the pelvic floor using RTUS have so far only been tested in healthy adult females (Sapsford, 2001).

The aim of this study is to evaluate if by using Real Time Ultra Sound biofeedback (RTUS), a non-invasive technique, patients with urinary stress incontinence can learn more quickly how to co-contract the Transversus Abdominis muscle (TrA) and Pelvic Floor Muscles (PFM) in order to rehabilitate the pelvic floor and thereby reduce or eradicate the distressful symptoms of leakage. If RTUS can shorten the number of sessions required for patients to learn correctly how to co-contract the pelvic floor muscles this would enable physiotherapists to see a greater number of patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Urinary incontinence

Interventions

Participants will be randomised into two groups, one with RTUS over the abdominal muscles to facilitate instructions to activate co-contraction of the pelvic floor muscles, and the other without real time ultra sound biofeedback. Assessment parameters include a leakage diary, a one hour pad test, and subjective evaluation of life impact questionnaire (Kings Health Questionnaire). Each group will be assessed after 12 weeks training.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The study is to evaluate if by using RTUS, patients with urinary stress incontinence can learn more quickly how to co-contrast the Transversus Abdominis muscle (TrA) and Pelvic Floor Muscles (PFM) in order to rehabilitate the pelvic floor and thereby reduce or eradicate the distressful symptoms of leakage. If RTUS can shorten the number of sessions required for patients to learn correctly how to co-contrast the pelvic floor muscles this would enable physiotherapists to see a greater number of patients .

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

01/03/2006

Eligibility**Key inclusion criteria**

Women between the ages of 30 and 65 with USI

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

40

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/2003

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Willesden Community Hospital

London

United Kingdom

NW10 3RY

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Research organisation

Funder Name

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