

Inko-Outside multicentre, controlled, randomised, blinded study for the treatment of stress urinary incontinence

Submission date 23/03/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 25/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/03/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

ClinicalTrials.gov (NCT)
NCT01472068

Protocol serial number
BMR-09-1008

Study information

Scientific Title

A single-blind multicentre, controlled, randomised, blinded comparative study of three forms of pelvic floor muscle training: kegel exercises (KE), electrical stimulation using external skin-electrodes (ESEX) and electrical stimulation using an intra-vaginal electrode (ESIN), in the treatment of stress urinary incontinence

Acronym

INKO-OUTSIDE

Study objectives

Comparison of three forms of pelvic floor muscle training in the treatment of stress urinary incontinence:

1. Kegel exercises (KE)
2. Electrical stimulation using external skin-electrodes (ESEX)
3. Electrical stimulation using an intra-vaginal electrode (ESIN)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board (IRB) of North Georgia College & State University

Study design

Randomised controlled single-blind multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stress urinary incontinence

Interventions

1. 12 weeks of treatment with Inko-Outside (external NMES) and 14 weeks of Kegels
2. 12 weeks of treatment with conventional NMES using an internal probe and 14 weeks of Kegels
3. 26 weeks of Kegels

Intervention Type

Mixed

Primary outcome(s)

Change in continence scores compared to baseline:

1. Incontinence impact questionnaire score (IIQ-7)
2. Pelvic Floor Muscle strength as determined by Modified Oxford Scale upon digital palpation:
 - 2.1. Pad usage
 - 2.2. Leaks per week
 - 2.3. Pad weight in provocative tests (cough and jumping jacks)
 - 2.4. Compliance measure on stimulators and on diary for PFMT
3. Number of participants who have gone on to have surgery at 1 year - follow-up phone call

Key secondary outcome(s)

1. Proportion of group cured (namely, dry at each visit):
2. Proportion of group improved
3. Time to dryness in weeks

Dryness will be defined as dry for 5 consecutive days as reported by subjects on enquiry, and which is subsequently maintained until the end of the study (26 weeks). The status will also be confirmed by provocative tests with cough and jumping jack activities in the clinic. Participants having been declared "dry" will be determined to have relapsed if they have more than 1 leak per week, with normal activities.

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Referrals with significant stress urinary incontinence (SUI) (defined as greater than 3 leaks/day or greater than 3 g in cough/jumping jack test) of any ethnic background
2. Pre-screened and cleared by gynaecological/urologist/suitably experienced PT for structural abnormalities (e.g. prolapsed uterus)
3. Body mass index (BMI) less than 40 kg/m²
4. Non-smoker
5. Greater than 3 months post-partum
6. Females at least 18 and less than 70 years of age
7. Able to comply with either therapy
8. Able and willing to complete all of the study and provide informed written consent prior to entering the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Persons contra-indicated for ES
2. Individuals with a history of an underlying neurological condition
3. Individuals with an active implanted medical device, e.g., pacemaker or pump
4. Pregnant women or inadequate precautions to prevent pregnancy
5. Neurological impairment affecting pelvic floor musculature

6. Medication affecting continence
7. Medication for high blood pressure
8. Previous incontinence surgery, hysterectomy, previous gynaecological related surgery
9. Intra-uterine devices (IUDs) or metal implants in the pelvic area, including hip
10. Clinical diagnosis of prolapse
11. Abnormal Pap smear in the previous 6 months

Date of first enrolment

12/04/2010

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

United Kingdom

Germany

Ireland

United States of America

Study participating centre

North Georgia College and State University

Dahlonega, Georgia

United States of America

30597

Sponsor information

Organisation

North Georgia College and State University (USA)

ROR

<https://ror.org/001pe5g24>

Funder(s)

Funder type

Industry

Funder Name

Bio-Medical Research Ltd (UK) - provided devices

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration