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

Submission date	Recruitment status	[X] Prospectively registered
23/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/03/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2019	Urological and Genital Diseases	[_] 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
Nil known

IRAS number

ClinicalTrials.gov number
NCT01472068

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
12/04/2010

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/m^2
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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
243

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
Germany

Ireland

United Kingdom

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)

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Sponsor type
University/education

Website
http://www.ngcsu.edu/

ROR
https://ror.org/001pe5g24

Funder(s)

Funder type
Industry

Funder Name
Bio-Medical Research Ltd (UK) - provided devices

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