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A study to look at the safety and performance of Neuromuscular Electrical Stimulation (NMES) with the NeuroTech Vital device compared to the itouch Sure Pelvic Floor Exerciser for the treatment of stress urinary incontinence

Submission date 24/02/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/03/2014	**Overall study status** Completed	
Last Edited 14/08/2020	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims

Stress Urinary Incontinence (SUI) is described as an uncontrolled loss of urine which happens while running, jumping and lifting, or simply sneezing or coughing. There are various treatment options which can be tried to help with this condition and one which has been used over a number of years is electrical stimulation that contracts and relaxes the pelvic floor muscles, which in turn strengthens the muscles and improves SUI . There are different ways of giving this stimulation to the pelvic floor muscles. Different devices can provide this type of treatment. This study aims to look at and compare treatments of two different devices: Neurotech Vital device (NTV) and the itouch Sure Pelvic Floor Exerciser. The NTV is a device which uses external electrodes to supply the electrical stimulation to the pelvic floor muscles (this is by wrapping a garment around the bottom/buttocks and tops of the legs), which is connected to a device which when turned on supplies the electrical stimulation. The itouch Sure Pelvic Floor Exerciser is a device that uses internal electrodes (by way of a vaginal probe which is inserted into the vagina) to provide electrical stimulation to the pelvic floor muscles.

Who can participate?

Women who have been diagnosed with stress urinary incontinence (SUI)

What does the study involve?

The study involves 12 weeks of treatment with either device, which is decided randomly. Both devices are used according to the manufacturer's instructions for use. Both devices are used at home and participants are followed by a research nurse and a physiotherapist at the clinic halfway through the treatment (6 weeks) and at the end of the treatment (12 weeks).

What are the possible benefits and risks of participating?

It is hoped that participants get some benefit from participation in this study with an

improvement in their symptoms. It cannot be promised that this study will help them but the information from this study will help improve the treatment of people with stress urinary incontinence. There are no expected risks to taking part.

Where is the study run from?
The Friarage Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2014 to May 2016

Who is funding the study?
Bio-medical Research Ltd (Ireland)

Who is the main contact?
Mrs Karen Robson
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Contact information

Type(s)
Scientific

Contact name
Mrs Karen Robson

Contact details
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2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BMR-14-1001

Study information

Scientific Title
A randomised, controlled, single-blind, pilot clinical study to evaluate the safety and performance of Neuromuscular Electrical Stimulation (NMES) with the NeuroTech Vital device compared to the itouch Sure Pelvic Floor Exerciser for the treatment of stress urinary incontinence in female patients

Acronym
NTV Pilot

Study objectives
To look at the safety and the performance of the Neurotech Vital device compared to the itouch Sure Pelvic Floor Exerciser, both used to treat Stress Urinary Incontinence in female subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - submission pending

Study design
Randomised controlled single-blind pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Uro-gynaecology (stress urinary incontinence - SUI)

Interventions
There are two arms to this study. Both are active treatments for SUI.

Neuromuscular Electrical Stimulation (NMES) with the Neurotech Vital device compared to the itouch Sure Pelvic Floor Exerciser.

Treatment duration: 12 weeks

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

The proportion of subjects considered to have achieved significant improvement following the 1-hour pad weight test at 12 weeks compared to baseline. Significant improvement is defined as a greater than 50% reduction in pad weight from baseline.

Secondary outcome measures
The following secondary endpoints will be analysed at 6 and 12 weeks and at 6 months compared to baseline.

1. Urine leakage following a 1-hour pad weight test (following standardized bladder-filling protocol verified by ultrasound)
2. Dryness, defined as a pad weight of less than 1 g on the 1-hour pad weight test
3. Proportion of subjects considered to have achieved significant improvement, defined as a greater than 50% reduction in pad weight, from baseline on the 1-hour pad weight test (6 weeks and 6 months)
4. Reduction in pad weight on 1-hour pad weight test in relation to the mean intensity of the stimulation delivered during the 12-week treatment programme
5. Quality of life assessed using the Incontinence Quality of Life Questionnaire (I-QOL) and Kings Health Questionnaire (KHQ)
6. Urine leakage experienced by the subject at home during a 24-hour period (24-hour pad weight test)
7. Dryness, defined as a pad weight of less than 1.3 g on the 24-hour pad weight test
8. Proportion of subjects considered to have achieved significant improvement, defined as a greater than 50% reduction in pad weight from baseline, on the 24-hour pad weight test
9. Number of incontinence episodes/day recorded using a 3-day voiding diary
10. Number of pads used/day recorded using a 3-day voiding diary
11. Pelvic floor strength and quality of contraction measured using the Modified Oxford Score

Other secondary endpoints will be:
11. Time to achieve dryness (i.e. no record of any leaks) on the 3-day voiding diary
12. Device compliance of the Neurotech Vital device with the treatment protocol during the 12-week treatment programme
13. Device compliance of the itouch Sure Pelvic Floor Exerciser with the treatment protocol during the 12-week treatment programme
14. Safety in relation to adverse events and device deficiencies reported
15. Subject feedback on the device recorded by the Device Ease of Use Questionnaire following completion of the 12-week treatment programme
16. Comparison of the 12 week Neurotech Vital device results with the 12-week itouch Sure Pelvic Floor Exerciser results.

Where appropriate, the above endpoints at 6 months will be compared to measurements at 12 weeks (completion of treatment programme).

Overall study start date
15/05/2014

Completion date
15/06/2015

Eligibility

Key inclusion criteria

1. Subjects who are female and at least 18 years of age
2. Subjects who have signed informed consent form prior to any study related activity
3. Subjects who have been clinically diagnosed with stress urinary incontinence and demonstrate a >2g and <90g urine leakage following a standardised 1-minute stress test at 1 hour post-bladder filling protocol (1-hour pad weight test) at the baseline assessment
4. Subjects who have less than 10 voids in a 24-hour period on the 3 day voiding diary
5. Subjects who have scored less than 9 out of 18 for the Urge Incontinence Questions and are confirmed as having predominant stress urinary incontinence on the Medical, Epidemiologic and Social Aspects of Aging Urinary Incontinence (MESA) Questionnaire completed at the screening assessment
6. Subjects with a Body Mass Index of ≤ 35 kg/m2
7. Subjects of child-bearing potential who are using a highly effective contraceptive method (established use of oral, injected, implanted hormonal method of contraception or barrier method of contraception with spermicide)
8. Subjects who are willing not to seek any other treatment for stress incontinence during the study period
9. Subjects who are able to give voluntary, written informed consent to participate in this study and from whom consent has been obtained
10. Subjects who are able to understand this study and are willing to complete all the study assessments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
10

Key exclusion criteria
1. Subjects who have an existing medical condition that would compromise their participation in the study
2. Subjects who have a physical condition that would make them unable to perform the study procedures
3. Subjects who have been diagnosed with Chronic Obstructive Pulmonary Disease (COPD)
4. Subjects with a history of an underlying neurological condition affecting urinary output
5. Subjects with any bladder abnormality that would affect the urinary flow through the urethra
6. Subjects with a history of low back pain involving the spinal nerve root
7. Subjects with a blood clotting disorder or who are taking anti-coagulant medications
8. Subjects who have previously had any uro-gynaecological related surgery that would affect the pelvic floor muscles or urinary flow through the urethra (excluding hysterectomy)
9. Subjects who have previously had pelvic floor radiation
10. Subjects who have previously been treated for stress incontinence with injectable bulking agents and/or vaginal probes within the past 6 months

11. Subjects with a clinical diagnosis of prolapse greater than Stage 2
12. Subjects who are pregnant or could be pregnant
13. Subjects who are less than 6 months post-partum or who are lactating
14. Subjects who have any intra-uterine devices or metal implants in the pelvic area, including hip and lumbar spine
15. Subjects with an active implanted medical device (i.e. pacemaker, pump etc)
16. Subjects with a current or active history of pelvic cancer and/or subjects with a life expectancy of less than 12 months
17. Subjects who are currently involved in any injury litigation claims
18. Subjects who have participated in a clinical study in the last 3 months or any previous clinical study with Bio-Medical Research Ltd
19. Subjects who have been committed to an institution by virtue of an order issued either by the courts or by an authority

Date of first enrolment
15/05/2014

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Ireland

United Kingdom

Study participating centre
Bio-Medical Research Ltd
Galway
Ireland
2

Sponsor information

Organisation
Bio-Medical Research Ltd (Ireland)

Sponsor details
Parkmore Business Park West
Galway
Ireland
2

Sponsor type
Industry

Funder(s)

Funder type
Research organisation

Funder Name
Bio-Medical Research Ltd (Ireland)

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