ISRCTN68358784 https://doi.org/10.1186/ISRCTN68358784

Safety and performance of Neuromuscular Electrical Stimulation (NMES) with the Neurotech Vital device for the treatment of stress urinary incontinence (SUI)

Submission date
23/07/2013

Recruitment status
No longer recruiting

Registration date
30/07/2013

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Stress urinary incontinence (SUI) is as an uncontrolled release of urine which happens during physical activities such as running, jumping and lifting or when simply sneezing or coughing. There are various treatment options available: surgical operations, pelvic floor exercises/muscle training (for muscles that are present below the pelvis region) and electrical stimulation. The aim of this study is to find out whether using the Neurotech Vital (NTV) device for 12 weeks can stimulate the pelvic floor muscle, making it stronger and in doing so improve SUI in women.

Who can participate?
Women who have failed a 6-week exercise programme and have been diagnosed with SUI

What does the study involve?
Participants are randomly allocated to use either the NTV or an altered NTV that does not give the same stimulation treatment. Participants wear the NTV device which includes a wired garment around the hip and bottom area for a period of 30 minutes, 5 days a week for 12 weeks. During this treatment electrical stimulation is passed through skin contact electrodes (large sticky black pads), which causes the pelvic floor to contract and relax, without participants having to do anything. This treatment is not painful and is very similar to the workout from relaxing and contracting the pelvic floor muscles, but the device produces a much stronger contraction. Participants who receive the altered NTV are offered the non-altered NTV after their first 12-week programme.

What are the possible benefits and risks of participating?
There are no anticipated risks to involvement in this study than would be expected for normal treatment of this condition with other devices which use electrical stimulation. Sensitivity to the skin contact electrodes could be possible but there is no reason to suspect that any reaction would happen or that there would be any long-term health problems.

Where is the study run from?
The study is already running in Germany and further sites will be opened in the UK

When is study starting and how long is it expected to run for?
January 2014 to April 2015

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

Who is the main contact?
Mrs Karen Robson
krobson@bmr.ie

Contact information

Type(s)
Scientific

Contact name
Mrs Karen Robson

Contact details
Bio-Medical Research Ltd
Parkmore Business Park West
Galway
Ireland
N/A
+353 (0)9177 4326
krobson@bmr.ie

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02214784

Secondary identifying numbers
BMR-11-1002

Study information

Scientific Title
A Randomised Controlled double-blind clinical Trial to evaluate the safety and performance of Neuromuscular Electrical Stimulation (NMES) with the NeuroTech Vital device for the treatment of stress urinary incontinence (SUI)

Acronym

NTV RCT

Study objectives
The purpose of this study is to test whether a 12-week programme of treatment with the Neurotech Vital (NTV) significantly improves the symptoms of stress urinary incontinence (SUI) in female subjects compared to a modified NTV device. This will be assessed by comparing a 1-minute stress test at 1 hour post-bladder filling protocol, a 24 hour pad weight test, quality of life questionnaires and completion of a 3-day voiding diary and incontinence episode over a 24 hour period. The primary objective is to show the reduction from baseline to 12 weeks in pad weight following a standardised 1-minute stress test at 1 hour post-bladder filling protocol and the improvement from baseline to 12 weeks in quality of life measured by the Incontinence Quality of Life Questionnaire (IQOL)

Ethics approval required
Old ethics approval format

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

Study design
Prospective randomised controlled double-blind multi-centre clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Screening, visit 1: patients are assessed for eligibility
Baseline visit 2: week 0 - patients are randomized to either get the Neurotech Vital (active group) or the modified Neurotech Vital (control group), 12 weeks treatment with either device
Follow up visit 3: 4 weeks later
Follow up visit 4: 8 weeks
Follow up visit 5: 12 weeks - end of treatment. Patients are asked if they are happy with the treatment they received if no, they are un-blinded and if they were allocated the modified device they can have a further 12 weeks treatment. If they had the active device they continue on to kegels and visit 6 (14 weeks later) and telephone call 7 and telephone call 8. Patients who

have a further 12 weeks treatment will go back to visit 0 baseline and continue right through to the telephone call 8.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Reduction from baseline to 12 weeks in urine leakage following a standardised 1-minute stress test at 1 hour post-bladder filling protocol (1-hour pad weight test)
2. Improvement from baseline to 12 weeks in quality of life, assessed using the Incontinence Quality of Life Questionnaire (I-QOL)

Secondary outcome measures
The following secondary endpoints will be analysed for the main and the cohort study at 4, 8 and 12 weeks and at 6 months compared to baseline.
1. Urine leakage following a 1-minute stress test at 1 hour post-bladder filling protocol (1-hour pad weight test) (except for the 12 week assessment which is one of the primary endpoints)
2. Dryness, defined as a pad weight of less than 1g on the 1-hour pad weight test
3. Significant improvement, defined as a greater than 50% reduction in pad weight from baseline on the 1-hour pad weight test
4. Reduction in pad weight on the 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) (except for the 12 week assessment which is one of the primary endpoints)
6. Quality of life, assessed using the Kings Health Questionnaire (KHQ)
7. Urine leakage experienced by the subject at home during a 24-hour period (24-hour pad weight test)
8. Dryness, defined as a pad weight of less than 1.3g on the 24-hour pad weight test
9. Significant improvement, defined as a greater than 50% reduction in pad weight from baseline on the 24-hour pad weight test
10. Number of incontinence episodes/day, recorded using a 3-day voiding diary
11. Number of pads used/day, recorded using a 3-day voiding diary
12. Pelvic floor strength and quality of contraction, measured using the Modified Oxford Score
13. Pelvic floor muscle function, measured using sonographic/real time ultrasound imaging /recording with displacement measurement using onscreen callipers on the sonogram unit to assess volitional contractions (only carried out at one site Sonja Soeder, Germany)

Other secondary endpoints will be:
1. Time to achieve dryness (i.e. no record of any leaks) on the 3-day voiding diary
2. Compliance with the treatment protocol during the 12-week treatment programme
3. Safety in relation to adverse events and device deficiencies reported
4. Subject feedback on the device recorded by the Device Ease of Use Questionnaire following completion of the 12-week treatment programme
5. The Kings Health Questionnaire and Incontinence Quality of Life Questionnaire (I-QOL) at 9 and 12 months
6. A comparison of the 12 week Neurotech Vital device results with the 12 week modified Neurotech Vital device results

Overall study start date
01/01/2014

Completion date
01/04/2015

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 previously failed a 6 week volitional pelvic floor muscle training programme or in the Investigators opinion an equivalent lifestyle and exercise programme
4. Subjects who have been clinically diagnosed with stress urinary incontinence and demonstrate a >4g urine leakage following a standardised 1-minute stress test at 1 hour post-bladder filling protocol (1-hour pad weight test). Stress urinary incontinence is defined as complaint of involuntary leakage on effort or exertion, or on sneezing and coughing (International Continence Society)
5. Subjects who 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 ≤ 40 kg/m2
7. Subjects who are able to give voluntary, written informed consent to participate in this study and from whom consent has been obtained
8. 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
140

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
5. Subjects with a history of low back pain involving the spinal nerve root

6. Subjects who are currently taking medication, or have taken medication in the last 4 weeks, for urinary incontinence or that effect urinary output function including anti-cholinergics or anti-histamines or any anti-anxiety medications
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 with a clinical diagnosis of prolapse greater than Stage 2
10. Subjects who are pregnant or could be pregnant
11. Subjects who are less than 6 months post-partum or who are lactating
12. Subjects who have any intra-uterine devices or metal implants in the pelvic area, including hip and lumbar spine
13. Subjects with pelvic pain or fibromyalgia or paravaginal defect
14. Subjects with an active implanted medical device (i.e. pacemaker, pump etc)
15. Subjects with a current or active history of pelvic cancer and/or subjects with a life expectancy of less than 12 months
16. Subjects with an injury or disability affecting any part of their body which will be in contact with the garment
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
20. Any vulnerable subjects defined as individuals whose willingness to volunteer in a clinical study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical and medical device industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent

Date of first enrolment
01/01/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Germany

Ireland

United Kingdom

Study participating centre

Bio-Medical Research Ltd
Galway
Ireland
N/A

Sponsor information

Organisation
Bio-Medical Research Ltd (Ireland)

Sponsor details
Parkmore Business Park West
Galway
Ireland
N/A

Sponsor type
Industry

Website
http://www.bmr.ie

Funder(s)

Funder type
Industry

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