ISRCTN74508432 https://doi.org/10.1186/ISRCTN74508432

Evaluation of a new technology to treat urinary incontinence in women

Submission date
10/08/2011

Recruitment status
No longer recruiting

Registration date
20/09/2011

Overall study status
Completed

Last Edited
31/01/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study has been designed to test a new device for the treatment of incontinence in women and to compare it with information on self managing the problem provided by the Continence Foundation. This new device has been developed by Femeda (a UK company producing products for the treatment of incontinence) and scientists at the University of Manchester.
This is an electrical stimulation device designed to stimulate the pelvic floor muscles. The device is similar in size and shape to a tampon, is comfortable to use and is inserted into the vagina using a plastic inserter. The device switches off automatically after 30 minutes. At this stage it can be removed and thrown away. This is the first time a disposable device has been tested on women, although the stimulation technology has previously been tested on women using a non-disposable device.

Who can participate?
200 women have been recruited to take part in this study. They are aged between 18 and 65 years and suffer from urinary incontinence, but are otherwise healthy.

What does the study involve?
The study is 18 weeks long and involves four (30-40 minute) visits at a specialist research centre in Manchester - the Wellcome Trust Clinical Research Facility (WTCRF). During the first visit a video is shown that describes the project in detail. Women are then given an opportunity to discuss the study and if agree to take part, sign a consent form. A physical examination is then undertaken by a qualified doctor. This involves palpation of the stomach and a vaginal examination to check for any infections or abnormalities. A sample of urine is also collected. Each woman then keeps a diary sheet to record any incontinent episodes for one week on four occasions throughout the study. The second visit is one week after the first. During this visit each woman fills in three questionnaires about the effects of incontinence on quality of life and on sex life. Each woman then receives information on managing incontinence which has been produced by the Continence Foundation.
Four weeks later everyone returns to the Research Facility for a third visit and fills out the questionnaires again. The women are then randomly assigned to one of two groups. One group receives the electrical stimulation device and the other group continues to manage their incontinence according to the recommendations from the Continence Foundation. Those

getting the device are asked to use this for 30 minutes per day for 12 weeks, except during a menstrual period. At the end of the 12 weeks the fourth visit takes place when the questionnaires about quality of life and sexual dysfunction are completed for the final time.

What are the possible benefits and risks of participating?
We are not aware of any additional risks or side effects though some women may find it a little inconvenient to use the device for 30 minutes per day. However, it can be used whilst carrying out normal activities, as for tampons, so we do not envisage too much inconvenience. We hope that the electrical stimulation device will have a great potential benefit in terms of improving symptoms of incontinence. The electrical stimulation device will be further developed until early 2012 and we envisage it will then be manufactured for sale in chemists and supermarkets to be freely available to all women. We hope it will be available in the UK in 2012-2013.

Where is the study run from?
The Wellcome Trust Clinical Research Facility (WTCRF), Manchester, UK.

When is the study starting and how long is it expected to run for?
The study started in May 2009 and is expected to run until the end of 2011.

Who is funding and overseeing the study?
Femeda the company producing the device.

Who is the main contact?
Professor Jackie Oldham
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Contact information

Type(s)
Scientific

Contact name
Prof Jackie Oldham

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FEMESTIM CIP 002

Study information

Scientific Title
Evaluation of a new technology to treat urinary incontinence in women: a single blind randomised controlled trial

Acronym
FEMESTIM

Study objectives
Null hypothesis: There will be no difference in outcome for women with urinary stress incontinence between those receiving standard written information about pelvic floor muscle exercises and those receiving this written information plus a novel electrical stimulation device (FEMESTIM) for restoring pelvic floor function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield Ethics Committee approved in January 2009, reference number 06/Q2308/134

Study design
Single blind randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Urinary incontinence

Interventions
All women are supplied with the same magazine article outlining current self help treatment for urinary incontinence.

The women in the novel stimulation device group are supplied with enough single use disposable electrodes to last them for twelve weeks of stimulation. Devices will be used for 30mins per day on a daily basis and switch on automatically on insertion into the vagina and switch off automatically after the 30mins time period after which time they are removed and discarded. Women in this group also receive an instruction leaflet regarding pelvic floor muscle exercises that should be undertaken during the course of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life measured at week 2, weeek 4 and week 12 through completion of the short form version of the International Consultation on Incontinence Questionnaire (ICIQ-UI)

Secondary outcome measures
1. Patient Global Impression of Severity and of Improvement
2. Sexual dysfunction questionnaire (ICIQ-FLUTSex)
3. Diary of stimulation use and compliance
Measured at week 2, weeek 4 and week 12

Overall study start date
01/05/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
All women:
1. Who suffer from stress incontinence
2. Who self refer
3. Who are interested in participating in the study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria

1. Age under 18 years or more than 65years
2. Lack of consent to stimulation
3. Pregnancy
4. Implanted pacemaker
5. Recent pelvic surgery (within last 3 months)
6. Recent haemmorhage / haematoma / tissue damage
7. Previous or at presently undergoing any active therapy for pelvic malignancy
8. Urinary tract infection
9. Vaginal infection
10. Atrophic vaginitis
11. Diabetes or neurological condition
12. Any lesions or other pathology of the vagina or labia
13. Manual dexterity insufficient to place the device
14. Previously had treatment for their urinary incontinence
15. Refusal to provide permission for general practitioner (GP) examination
16. GP determination that the patient is not suitable for participation in the investigation
17. Had baby within the previous 3 months

Date of first enrolment
01/05/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Rehabilitation Science
Manchester
United Kingdom
M1 7DN

Sponsor information

Organisation
Femeda Ltd (UK)

Sponsor details
Westminster Business Centre
Lion Court
Hanzard Drive

Wynyard Business Park
Wynyard
United Kingdom
TS22 5FD

Sponsor type
Industry

Website
http://www.femeda.com

ROR
https://ror.org/02c19c733

Funder(s)

Funder type
Industry

Funder Name
Femeda Ltd (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No