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Comparison of FemSoft® urethral insert and vaginal tampons for stress urinary incontinence

Submission date
03/08/2011

Recruitment status
No longer recruiting

Registration date
24/08/2011

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Urological and Genital Diseases

[_] 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 incontinence is the most common form of incontinence. It means you leak urine when you increase the pressure on the bladder, as in coughing, sneezing or exercise. The aim of this study is to find out about the effectiveness of a device (FemSoft) for female stress urinary incontinence. The FemSoft insert is a soft silicone sleeve containing mineral oil that is inserted into the urethra (the outlet for urine) to prevent leakage. It is retained in place by a soft, fluid-filled balloon that lies just within the neck of the bladder. FemSoft was introduced in the USA in 1998 and was subjected to extensive studies before being approved for use in adult women by the Food and Drug Administration (FDA). It has been available on the US market by doctor's prescription for over 10 years and is now available in the UK on prescription.

Who can participate?
Women aged over 18 with moderate to severe (at least one episode per day on average) stress urinary incontinence.

What does the study involve?
Participating women will be randomly allocated to one of two groups. One group will use FemSoft and the other will use a vaginal tampon. After receiving extensive training, each participant will use the allocated device for one week's trial to ensure familiarity before proceeding with recording the number of times leakage occurs whilst using the device for a period of 6 weeks. After the 6 weeks the participants will be invited back to the clinic for follow up and to complete questionnaires about their attitudes and perception of the device and to make an assessment of any improvement in their quality of life.

What are the possible benefits and risks of participating?
The possible benefits to participants include the chance to try a new treatment for stress urinary incontinence. Patients will be able to continue using the FemSoft device if it proves to provide appropriate relief from symptoms. There are some risks associated with the use of FemSoft. Migration of the device into the bladder; this is a rare occurrence and the device would have to be removed by a simple medical procedure called cystoscopy, which involves putting a thin tube up the urethra. Expelling the device during use; a very small percentage of women have experienced this. There is an increased risk of urinary tract infection during the first few days of

use, when it is thought that unfamiliarity can lead to contamination of the device before insertion. Scrupulous attention to training and hygiene will reduce this and, after the initial training period, the incidence of urinary tract infection falls to a level normally found throughout the adult female population. Bleeding from injury to the skin around the opening to the urethra; this was usually during the initial training period when women were learning how to insert FemSoft, and no treatment was necessary when this occurred during the initial study. Blood spots; three women in the study noticed blood after withdrawal.

When is the study starting and how long is it expected to run for?
It is anticipated that the first candidate will be enrolled early in August 2010 and the study will be completed by December 2012.

Where is the study run from?
Derriford Hospital (UK).

Who is funding the study?
The trial is funded entirely by a research grant provided by Rochester Medical, the manufacturers of FemSoft.

Who is the main contact?
Professor Robert Freeman
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3.0

Study information

Scientific Title
A randomised controlled trial comparing the use of a urethral insert, (FemSoft®) with vaginal tampons in the management of female stress urinary incontinence

Study objectives
Does an intra-urethral device reduce the number of stress urinary incontinence (SUI) episodes compared with an intra-vaginal tampon?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee East of England - Cambridge East, 23/06/2011, ref: 11/EE/0183

Study design
Single-blind single-centre parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Female stress urinary incontinence

Interventions
Eligible participants will be assigned to a treatment group using computer generated randomisation in blocks, with allocation from a central office. Either device will be used, firstly for a training week to get used to the device and then for a further 6 weeks, during which voiding and incontinence diaries will be kept, after which the subject will be seen again at clinic and the following recorded:
1. Voiding and incontinence episodes diary will be returned
2. International Consultation on Incontinence Questionnaire - Short Form (ICI-Q SF)
3. Quality of life I-QoL, SF36

4. Patient goals
5. Urine microbiology
6. Patient Global Impression of Improvement (PGI-I) and Patient Global Impression of Severity (PGI-S)
7. Urgency perception scale
8. Satisfaction with device - Visual Analogue Scale (VAS)

Intervention Type
Device

Primary outcome measure
1. Number of incontinence episodes per week (from voiding diary) whilst wearing a device
2. The primary outcome will be compared between the two groups in two ways - number of episodes (either with appropriate non-parametric tests or generalised linear models, since incontinence episodes typically follow a Poisson distribution), and a separate comparison of subjects reporting no episodes that is those reporting continence whilst using the device (if there are sufficient of these)

Secondary outcome measures
1. Incontinence severity and bother score measured by ICI-Q SF questionnaire
2. Patient global assessment of improvement (post treatment only) and severity by PGI-I and PGI-S
3. Urgency perception scale (Cardoza et al, 2005)
4. Quality of life I-QoL, SF36
5. Patient goals
6. Urine microbiology (initially test strip - if positive an mid stream specimen (MSU) will be taken for culture
7. Secondary outcomes will be compared between groups using parametric or non-parametric tests appropriate for the types of measures

Overall study start date
01/08/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Female participants over 18 years of age
2. Not pregnant and if of child-bearing age agrees to use reliable contraception throughout the trial
3. Able and willing to use tampons
4. Sufficient mobility / dexterity to use device and competent mentally
5. Able to give consent
6. Confirmed moderate to severe (at least one episode per day on average) SUI or mixed incontinence that is SUI predominant (cough test or urodynamic assessment)
7. Period of trial representative of normal activities (e.g. does not include a holiday)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
A total of 90 subjects divided randomly into two groups of 45

Key exclusion criteria
1. Body mass index (BMI) > 40
2. Previous surgery for SUI
3. Pelvic organ prolapse (POP) > stage 2
4. Using medication to treat urinary incontinence such as anticholinergics or duloxetine
5. History of recurrent urinary tract infections or signs and symptoms of a urinary tract infection
6. Signs and symptoms of vaginal / urethral irritations
7. Post residual volumes greater than 200 ml
8. Unable to understand instructions for use of the device

Date of first enrolment
01/08/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation

Rochester Medical Ltd (UK)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Rochester Medical 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