Evaluation of the patients* satisfaction and safety of a non-degradable urethral bulking agent for female stress urinary incontinence

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Primary Objective: To determine the subjective improvement of symptoms in women with SUI treated with PDMS (Urolastic®)Secondary Objectives: - To determine the patients* satisfaction- To determine the complications and re-intervention rate- To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON46734

Source
ToetsingOnline

Brief title
Euro study

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
stress urinary incontinentce, urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: safety, satisfaction, Stress urinary incontinence, urethral injection therapy

Outcome measures

Primary outcome

Improvement of symptoms assessed by the patients global impression of improvement (PGI-I)

Secondary outcome

1. Patient satisfaction on results of the treatment by assessed by three validated questions

2. Number of procedure related adverse events: hematoma, urinary retention, urgency incontinence, pain, dyspareunia, urinary tract infection, infection at the injection site, exposure or erosion of the bulk material.

3. Re-intervention rate: number of re-injection and excision of PDMS and other surgical treatments for persistent or recurrent SUI after PDMS.

4. Objective cure assessed by cough stress test

Study description

Background summary

Urinary incontinence (UI) is a major public health issue affecting up to 25-50% of all women and has a detrimental impact on patient quality of life (1,2). Stress urinary incontinence (SUI) is the most common form of urinary incontinence and is defined as the leakage of urine, which occurs during physical activity of exertion or on sneezing or coughing. It has been reported that the prevalence of SUI is 25 to 45% of the female population (3,4).

Pelvic floor physiotherapy is the first choice of treatment and its aim to

strengthen the natural tissue support has a 33-49% chance of being effective (5,6). Nowadays, if pelvic floor exercises fail, mid-urethral slings (MUS) are widely used as a first-line surgical treatment. Over time, MUS has been evaluated to be a highly effective treatment. Subjective and objective cure rates of 91% and 85% respectively are reported (6).
An alternative treatment for SUI is urethral injection therapy. The hypothetical mechanism of action is that by the injection of bulking agents (BA) into the urethral submucosa, artificial urethral cushions are created that can improve urethral cooptation and hence restore continence (7). Ideally, a BA should be permanent and maintain its shape, giving a long-lasting effect. In addition, BA should be biocompatible, non-degradable, non-allergenic, non-immunogenic and does not migrate. Over decades, various bulking agents have been developed and applied. Their biomechanical properties, effectiveness and safety vary depending on which synthetic or biological materials were used for the manufacturing of the bulking agent. A procedure with BA is performed in an outpatient setting under local analgesia which can be beneficial as compared to a tension free vaginal tape (TVT) procedure. In addition, a meta-analysis confirmed that voiding dysfunction was less present in BA as compared to open surgery (8). However, a Cochrane review states that there is insufficient data to guide practice. Relief of SUI symptoms up to 12 months is reported, but the results are inferior to open surgery. The lack of data on long-term effectiveness makes that BA is not recommended as a first-line treatment. Currently, only a small area of indications is reserved for BA as a treatment for SUI. BA is used in patients who are unfit for surgery for patients with recurrent SUI (RSUI) after MUS. Finally, some patients have a strong preference for minimally invasive therapy and accept a lower cure rate for injectable therapy over open surgical procedure (9,10).

In 2011 a new urethral BA was developed called Urolastic®. Urolastic® consists mainly of a non-degradable, biocompatible polydimethylsiloxane (PDMS) polymer. It remains flexible and adapts itself to the shape of the environment during injection, reducing the chances of internal migration. Although small prospective cohort studies on the safety and efficacy of Urolastic® have been published, the results vary significantly (11-16). Reported objective success rates range from 59,3 to 89%, subjective success rates range from 35,1 to 90% and complication rates vary from 16,3 to 30% (11-16). Possible reasons for this wide range could be due to the patient selection, time of follow-up and the learning curve of the physician. Nevertheless, these data are insufficient to determine whether Urolastic® is a reasonable treatment option for women with SUI.

The aim of this cross sectional research is to determine the subjective improvement of symptoms in women, the patients* satisfaction, the safety and re-intervention rate of women who have been treated with PDMS (Urolastic®).
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Study objective

Primary Objective: To determine the subjective improvement of symptoms in women with SUI treated with PDMS (Urolastic®)

Secondary Objectives:
- To determine the patients* satisfaction
- To determine the complications and re-intervention rate
- To determine the objective cure

Study design

Retrospective study

Study burden and risks

No extra risk is associated with the study. Patients have to revisit the hospital for physical examination and to fill out one questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women:
- > 18 years
- who underwent treatment with bulkinjection therapy Urolastic for stress urinary incontinence

Exclusion criteria

Incapable of giving informed consent

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2019
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL62993.018.17