Urolastic® versus Bulkamid® in treatment of female stress incontinence: randomized controlled trial.

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Subjective cure of urinary stress incontinence at 12 months after intervention and comparison of a new bulking agent Urolastic ® with Bulkamid® in the treatment of stress urinary incontinence. Our hypothesis: based on our study and literature...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urethral disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON41728

Source
ToetsingOnline

Brief title
Urolastic® versus Bulkamid® in treatment of female SUI

Condition

- Urethral disorders (excl calculi)

Synonym
female stress urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Urogyn B.V
Source(s) of monetary or material Support: Urogyn

Intervention

Keyword: bulking agent, female stress incontinence

Outcome measures

Primary outcome

The subjective cure rate of stress incontinence after either Urolastic® or

Bulkamid ® procedure performed under local anesthesia

Secondary outcome

Subjective cure rate of stress incontinence at 6 weeks, 3 months, 1 and 2 years

after the treatment with either Urolastic ® of Bulkamid®

Objective cure rate of stress incontinence at 6 weeks, 3 months, 1 and 2 years

after the treatment with either Urolastic ® of Bulkamid®

Complications after the procedure

Postoperative pain score

Patient satisfaction

Study description

Background summary

Stress urinary incontinence (SUI) is a common complaint which significantly impacts the quality of life of many women. It is caused by either sphincter abnormalities and/or urethral hypermobility and is characterized by involuntary urine loss during coughing, sneezing, physical exertion or sudden changes of position (Blaivas JG, 1997; Abrams P, 2003). Approximately 35% of women >18 years are suffering from involuntary urine loss. At the age of 60 years, the rate rises to 45% in Europe (Mohr S, 2011). Nowadays mid-urethral sling (MUS) procedures are widely used and highly effective in the treatment of SUI with a relatively low complication rate. Based on industry estimates there were approximately 250,000 of these procedures performed in the USA in 2010 (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm.) Although the efficacy of MUS

procedures is high, there is still a failure rate of about 10-20%.
In July 2011, the FDA issued a safety communication regarding the use of synthethic vaginal mesh for the treatment of pelvic organ prolapse and urinary stress incontinence stating that serious complications are not rare. According to this communication, the FDA received from January, 1 2008 through September, 30, 2011, 1,876 reports of complications associated with surgical mesh devices used to repair SUI. The most common complications reported through Medical Device Reports in descending order of frequency, include: pain, mesh erosion through the vagina, infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. Many of these complications require additional medical intervention, and sometimes require surgical treatment and/or
hospitalization.
(http://www.fda.
gov/medicaldevices/safety/alertsandnotices/ucm262435.htm) Therefore there is definitely a place for less invasive treatment of SUI. According to the study of Robinson Anders and colleagues, the majority of women with SUI would prefer a minor procedure with a lower risk of complications and are content to accept a lower success rate (Anders, R.D, 2003). Moreover, study of Steven Petrou has also shown that SUI patients are willing to accept a relatively low success rate for injectable therapy compared to open surgery (Petrou, S.P, 2006). Therefore less invasive therapies such as injectable therapy is an attractive option to patients who accept this form of treatment despite their lower success rate in comparison with more invasive methods as MUS.
Urethral bulking agents with specially designed injection devices are one of the minimally invasive options in the treatment of stress urinary incontinence. Bulking agents can be useful when patients experience MUS failure, have severe comorbidity (and thus a contraindication for general anesthesia), or when patients prefer minimally invasive surgery. The ideal bulking agent should be easily injectable under local anesthesia, should be permanent and maintain its shape, volume and flexibility and therefore its mechanical effect, and should be hypoallergenic and non immunogenic. One of the examples of bulking agents is Bulkamid®, which consists of a biodegradable gel (polymer gel composed of 2.5A% cross-linked polyacrylamide and 97.5% non-pyrogenic water) containing non degradable particles. The gel is injected trans urethrally at 3 places around the bladder neck, which results in the compression of the urethra. Although it contains non-biodegradable particles it stays liquid and is not easily encapsulated in scar tissue in the desired shape. Because of gel degradation, the volume of the implant may shrink and thereby diminish the therapeutic effect. Recent reports by Lose et al. and Toozs-Hobson et al. show that 135 women with either stress or mixed urinary incontinence have been treated with Bulkamid and followed for 12 and 24 months. The subjective response rate was 66% and 64% respectively (Lose, G et al. 2010, Toozs-Hobson et al , 2011).
Urolastic® has been developed as an improved alternative to the existing urethral bulking agents. Urolastic is a polydimethylsiloxane (PDMS) polymer. It is a minimally invasive, easy to inject and polymerizing in situ into a uniform

elastomer within seconds after application. It remains flexible and adapts itself to the shape of the environment during injection, reducing the chances of migration. Reflux of the material after injection as a consequence of the interstitial pressure is unlikely after polymerization. The product is biocompatible; it is not biodegradable, resulting in a long term effect. The study by Zajda 2013 shows that after one year of treatment 72% of patients did not have any urinary incontinence whereas the Stamey incontinence grade improved significantly (Zajda et al., 2013) Furthermore, the results of 24 months follow-up after Urolastic injection indicate that 66% of the patients show significant improvement of stress urinary incontinence (SUI) (Zajda et.al 2014 submitted). In a recent study by Futyma et al it has been shown that the objective success rate in 54 patients with recurrent SUI was 59.3% including 45 patients who are completely dry 12 months after the procedure (Futyma et al 2014).
Since Bulkamid ® is a gel, it can degrade, and thereby lessen the effect on continence. Frequently (30% of the cases), repeated injections are necessary. Urolastic ® remains its shape and therefore the re-injection rate is much lower (approximately 0-2%) (Lose G et al.2010, Toozs-Hobson P et al, 2012).
In order to compare these two injectibles we propose a prospective randomised controlled trial to evaluate the subjective and objective outcome of Urolastic® or Bulkamid® in patients with symptomatic stress incontinence, and the number of re-injections in both groups.

Study objective

Subjective cure of urinary stress incontinence at 12 months after intervention and comparison of a new bulking agent Urolastic ® with Bulkamid® in the treatment of stress urinary incontinence.
Our hypothesis: based on our study and literature available we expect Urolastic® as compared with Bulkamid® to be more successful in correction of stress urinary incontinence.
Primary objectives:
* Comparing the re-injection rate between Urolastic ® and Bulkamid ® treatment

Secondary objectives:
- Subjective cure of stress incontinence at 6 weeks and one and two years follow up after either Urolastic ® or Bulkamid® treatment
- Objective cure of urinary stress incontinence
- Improvement of stress incontinence
- Complications during and after the procedure
- Patient satisfaction

Study design

The proposed research concerns a single-centered, single blinded, randomized controlled clinical trial and is aimed to determine the effectiveness of Urolastic® compared to Bulkamid® in women with urinal stress incontinence. The participating hospital is Isala kliniken Zwolle (coordinator H.W.F van Eijndhoven, MD,PhD and M.K. Engberts, MD, PhD).
After inclusion patients will be randomly assigned to one of the study groups.

Intervention

Urolastic ® or Bulkamid ®

Study burden and risks

As we compare two strategies that are already applied in current practice, no additional risks from both procedures are expected. In several retrospective studies, it has been shown that injection of bulking agents is a safe procedure. Complications rarely occur and are usually minor, consisting mostly of temporary urinary retention, and urinary tract infection

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

a. Female is at least 18 years old
b. Moderate to severe incontinence according to the Sandvik Score incontinence scale with a duration of at least 12 months
c. Written informed consent
d. No contra-indications for Urolastic/Bulkamid injection at the site of the bladder neck or external urethral sphincter
e. Patient is mentally competent and able to understand all study requirements and agrees to be available for the follow-up evaluations as required by the protocol
f. Patient should not be on anticholinergic treatment unless they have been on stable treatment during the previous month and will continue treatment during protocol
g. Patient has good bladder function (bladder capacity at least 300 ml and post void residual <100ml
h. Patient of childbearing potential must use adequate contraceptive methods (oral contraceptive, IUD, double barrier device
i. Positive cough test with comfortable full bladder

Exclusion criteria

a. Women with history of vesicoureteral reflux, predominantly urgency incontinence
b. Women who used indwelling catheters for a long period of time and have fibrosis of the tissue at the injection sites
c. Women with a psychiatric or progressive neurological or muscular disease or other diseases with life expectancy of less than 1 year
d. Women with a previous implantation of an artificial urinary sphincter
e. Women who are pregnant, lactating or planning to become pregnant in the 2 years after treatment with Urolastic®/Bulkamid®
f. Women who underwent radiotherapy of the pelvis and/or perineum and have fibrosis at the likely injection sites
g. Patients having pelvic floor exercises, bladder training or other treatment for their urinary incontinence programmed during the study
h. Women with stage 2 or more genital prolapse, according to the ICS-Classification
i. Women who are not capable of giving informed consent
j. Women diagnosed with a urinary tract infection: cystitis (bacteriuria >100.000cfu/ml) or urethritis
k. Women with a bladder capacity <250 ml, based on a 48 hours voiding diary
l. Women with a history of AIDS or patients tested positive for HIV

m. Women with neurogenic incontinence
n. Women with urethral diverticulae
o. Women with detrusor overactivity unless stable with anticholinergic medication
p. Women having any condition which could lead to significant post operative complications, including uncontrolled diabetes, or elevated residual urine from bladder outlet obstruction
q. Women with one of the following conditions: abnormal post void residual (more than 150cc), urethral stricture and bladder neck contracture, spastic bladder, vesicourethral reflux, , bladder stones, bladder tumors, Conditions Posing Additional Risks, Concurrent Medication, Prior treatment, Contraindications and Warning Related to the Control Therapy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2015
Enrollment:	68
Type:	Actual

Medical products/devices used

Generic name:	Urolastic
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-04-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL51733.075.14