Cost-effectiveness of a Non-degradable Urethral Bulking Agent as compared to Mid-urethral Sling surgery in women with Stress Urinary Incontinence

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We propose a study to compare the cost-effectiveness of the new UBA to MUS surgery.

Ethical review	Approved WMO
Status	Completed
Health condition type	Genitourinary tract disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49210

Source
ToetsingOnline

Brief title
BAM study

Condition

- Genitourinary tract disorders NEC

Synonym
urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonmW,Urogyn BV

Intervention

Keyword: cost-effectiveness, mid-urehtral sling surgery, stress urinary incontinence, urethral bulking agent

Outcome measures

Primary outcome

The primary outcome of this study is subjective improvement assessed by the

1-item questionnaire *Patient Global Impression of Improvement* (PGI-I). The

PGI-I has a 7-point Likert scale with a response range from *very much worse*

to *very much better*. Improvement is considered to be clinically significant

when answers to the PGI-I are either *much better* or *very much better*.

Subjective improvement will be assessed at 4-6 weeks, 6 months and 12 months.

Secondary outcome

- Economic evaluation

- Subjective cure

- Objective cure

- Morbidity and complications

- Disease specific quality of life

- Seksual function

- Re-interventions

- Patient preference

Study description

Background summary

Urinary incontinence (UI) is a major public health issue affecting up to 29-57%

of all women. In 2014 only in the Netherlands, 150 million Euros were spent on incontinence material. Stress urinary incontinence (SUI) is the most common type of UI 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% in women aged over 40.
Subjective cure rates of mid-urethral sling (MUS) surgery reported in the most recent Cochrane review were 62-97%. An alternative surgical procedure involves urethral bulking agents (UBA), during which via the urethra, or peri-urethral, a biomaterial is injected to compress the mid-urethra. Reported efficacy rates are lower as compared to those of MUS surgery, due to migration of the biomaterial. However the exact indication of UBA has not been well established and practice variation exists.
Recently, a new type of UBA was developed, which a theoretically much lower risk on migration. This UBA consists of polydimethylsiloxane (PDMS) (brand name: Urolastic. Urogyn BV, Nijmegen, Netherlands) was introduced. The hypothetical mechanism of action of UBA is that by the injection of a biomaterial into the urethral submucosa, artificial urethral cushions are created that can improve urethral coaptation and hence restore continence. The unique feature of the new type of UBA is that PDMS polymerises in situ forming into an uniform elastomer that adapts itself to the environment during injection. This results in a large, non-degradable homogeneous mass that becomes encapsulated by the body as a whole and, as a result, can, theoretically, not migrate. Moreover, since this material is non-absorbable it is hypothesized that PDMS will give a long lasting effect. A small study prospective cohort study reported an overall success-rate of 89% after 12 months follow up, which is similar to the success of MUS surgery.
As compared to as MUS surgery, UBA has some advantages. First of all, UBA has a better safety profile (no risk to perforate visceral organs of the pelvic cavity). Secondly, the procedure is done under local anesthesia. Finally, the procedure is performed in an outpatient setting.Therefore, UBA can be more cost-effective than MUS-surgery.

Study objective

We propose a study to compare the cost-effectiveness of the new UBA to MUS surgery.

Study design

Prospective, matched-controlled cohort studie with a follow-up of 12 months.

Study burden and risks

In this research study we will evaluate two standard treatments for SUI: UBA and MUS-surgery. The burden of the research is minimal (questionnaires, 1 outpatients visit and 1 telephonic consult) and the investigation itself brings no additional risk for the subject.
Therefore the risk of this research is negligible.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Subject is at least 18 years of age
2. Subject has bothersome, moderate or severe SUI or stress predominant mixed urinary incontinence (Sandvik severity scale of 3 and higher).
3. Subject has decided to undergo a MUS-operation or treatment with UBA *Urolastic**
4. Subject has a positive result on the standardized cough stress test
5. Subject is willing and able to comply with the follow-up regime

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Subject has predominating urge incontinence
2. Subject has a genital prolapse with a POP-Q score of point Aa or Ba >/=0
3. Subject has had previous treatment with UBA.
4. Subject is pregnant or intends to become pregnant during the study.
5. Subject has a untreated urinary tract infection
6. Subject has a bladder capacity of <250ml
7. Subject has a post-voiding residu of >150ml
8. Subject has a flow of <15ml/sec
9. Subject is not capable 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:	Completed
Start date (anticipated):	09-03-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	22-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2019
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

ID: 21563
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59107.018.16
OMON	NL-OMON21563

Study results

Date completed:	13-10-2021
Results posted:	05-08-2022
Actual enrolment:	216

First publication
05-08-2022