Een onderzoek naar de kosten en effectiviteit van de mid-urethrale slingoperatie in vergelijking met bulkinjecties bij vrouwen met stressincontinentie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21563

Source
Nationaal Trial Register

Brief title
BAM study

Health condition

Stress urinary incontinence

Sponsors and support

Primary sponsor: Amsterdam University medical center
Source(s) of monetary or material Support: Urogyn BV unrestricted grand

Intervention

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) (Appendix A). 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

• Subjective cure defined as patients answering negative at the question: ‘Do you experience urine leakage related to physical activity, coughing or sneezing?’ This will be assessed at 4-6 weeks, 6 months and 12 months

• Patients Global impression of severity, which is a validated 1-item questionnaire (Appendix B). The Patient Global Impression of Severity (PGI-S) will be assessed prior to the intervention, at 4-6 weeks, 6 months and 12 months. The PGI-S has a 4-point Likert scale. The response on the question: “Check the number that best describes best what your urinary tract condition is at this point” ranges from ‘normal’ to ‘severe’. The PGI-S will be assessed prior to the intervention at 4-6 weeks, 6 months and 12 months.

• Objective cure by means of the cough stress test in lithotomy or supine position. The CST will be assessed prior to the intervention, at 4-6 weeks and at 12 months.

• Morbidity which is reported per- and post procedurally using the Clavien Dindo classification. Pain and procedure related discomfort will be assessed by a patient diary. This diary includes a visual analogue scale which measures pain, and consists of two questionnaires:

o 1. The validated AMC disability scale: item bank that assesses patients’ functional disability concerning activities of daily life (ADL) (getting in and out of bed, dressing and undressing, picking an object from the floor, walking) at interval level.

o A self-developed questionnaire consisting of questions that evaluate the presence and experienced bother of pain, being impaired in self-care or having impaired mobility after surgery. Each of these questions consists of two parts. The first part asks whether or not a type of discomfort is present. The second part of the question asks about the degree of bother that is experienced from that symptom. This is recorded on a four-point Likert scale: not at all, slightly, moderately or very much. Patients are asked to fill out the diary prior to the intervention and at day 0,1,2,3,7,14 and 28.

• Disease specific quality of life is measured by the validated short version of the Dutch validated Urogenital Distress Inventory (UDI-6) (Appendix D), the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Pelvic Organ Prolapse/Urinary Incontinence (Appendix E)

• Sexual Function Questionnaire (PISQ-IR) (Appendix F). Combined, this questionnaire consists of 26 questions. This questionnaire will be assessed at 4-6 weeks, 6 months and 12

months.

• Performed re-interventions: re-injections of Urolastic, PFMT and MUS are recorded in both groups.

• Economic evaluation: EQ5D (Appendix G) is used to establish health outcomes of the patient. Also, a diary evaluation costs (using IMCQ and IPCQ) needs to be filled in by patients prior tot the intervention, 4-6 weeks, 6 months and 12 months after intervention.

Study description

Study objective

It is hypothesize that a non-degradable urethral bulking agent (UBA) is non-inferior in efficacy and superior in cost-effectiveness as compared to mid-urethral sling (MUS) surgery in the treatment of moderate to severe stress urinary incontinence SUI.

Study design

Before treatment

T=0: informed consent, fill out first part of diary of discomfort and pain, fill out questionnaire (baseline, PGI-S, Sandvik severity scale, UDI-6, IIQ-7, PISQ-IR, EQ-5D-5L). Also the urinary flow + postresidual volume and 48-h voiding diary has to be completed if not already done (this is standard care).

Treatment

T=1: undergo treatment with UBA or MUS-surgery; as described in chapter 5.

After treatment

T=2: fill out diary of discomfort and pain at day: 0,1,2,3,7,14 and 28.

T=3: outpatient visit at 4-6 weeks: pelvic floor examination, standardized CST, questionnaire (PGI-I, PGI-S, Sandvik severity scale, UDI-6, IIQ-7, EQ-5D-5L)

T=4: telephonic consult at 6 months: evaluate extra outpatient visit, (S)AE, questionnaire (PGI-I, PGI-S, Sandvik severity scale, UDI-6, IIQ-7, PISQ-IR, EQ-5D-5L, patient satisfaction)

T=5: outpatient visit at 12 months: pelvic floor examination, standardized CST, questionnaire (PGI-I, PGI-S, Sandvik severity scale, UDI-6, IIQ-7, PISQ-IR, EQ-5D-5L, patient satisfaction)

Intervention

arm 1: Urethral bulkinjection therapy (urolastic)

arm 2: mid-urethral sling surgery

Contacts

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Eligibility criteria

Inclusion criteria

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

1. Subject is female

2. at least 18 years of age

3. Subject has bothersome, moderate or severe SUI or stress predominant mixed urinary incontinence (Sandvik severity scale ¡Ý 3 (Appendix C)).

4. Subject has decided to undergo a MUS-operation or treatment with UBA ¡°Urolastic¡¯¡±

5. Subject has a positive result on the standardized cough stress test

6. Subject is willing and able to comply with the follow-up regime

Exclusion criteria

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 type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2016

Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion
Date: 30-10-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49210
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7382
NTR-old	NTR7590
CCMO	NL59107.018.16
OMON	NL-OMON49210

Study results