Single incision sling versus Bulkamid in treating SUI

No registrations found.

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

Summary

ID

NL-OMON23096

Source
NTR

Brief title
TBA

Health condition

Stress urinary incontinence

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Isala

Intervention

Outcome measures

Primary outcome

To record patient satisfaction to treatment of stress incontinence (Patient Global Impression of Improvement) at 1 year follow up after Altis® procedures administered under conscious sedation with local infiltration or Bulkamid (PAHG).

Secondary outcome

1. Subjective cure of stress incontinence at 3 months, 1 year and 5 years after surgery
2. Objective cure of stress incontinence at 3 months, 1 year and 5 years after surgery
3. Complications during and after the procedure
4. Pain scores postoperative
5. Cost-effectiveness of the treatment

Study description

Background summary

Stress urinary incontinence (SUI) is a common complaint which significantly impacts the quality of life of many women. If the first-line treatment for SUI, the training of pelvic floor muscles, is insufficient, treatment options consist of transurethral bulking injection or midurethral sling placement. Midurethral slings are considered the gold standard for the treatment of SUI, with an efficacy as high as 90%. Bulking agents create an artificial mass into the urethral submucosa and according to hypothesis improve urethral coaptation and restore continence especially when abdominal pressure is increased. The efficacy of bulking agents in treating stress urinary incontinence has varied from 64% to 74% depending on the treated patient group, however, urethral injections have a lower risk of complications than midurethral sling surgery.
Studies comparing urethral injection treatment and single incision mid-urethral slings in women with pure stress urinary incontinence are scarce. Recently, a Finnish study group published their results on retropubic TVT versus PAHG-injections with Bulkamid ®. TVT was superior to Bulkamid ® in curing stress urinary incontinence. However, there were no complications in the Bulkamid ® group and patient satisfaction (‘would you choose this procedure again’?) was equal in both groups. Since single-incision slings are more often used than retropubic TVTs in the treatment of stress urinary incontinence in the Netherlands, this prospective observational cohort study compares the single-incision sling (Altis ®) and Bulkamid®-injections in treatment of SUI.

Study objective

The patient satisfaction between urethral injection treatment and single incision mid-urethral slings in women with pure stress urinary incontinence will be comparable. Patients treated with single incision mid-urethral slings will be more objectively dry, but patients treated with urethral injections will have less complications.

Study design

6 weeks, 3 months, 1 year

Intervention

• Single incision mid-urethral sling (Altis)

• Urethral injection treatment (Bulkamid)

Contacts

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Eligibility criteria

Inclusion criteria

• Predominant stress urinary incontinence (e.g. on a weekly basis more incontinence episodes related to physical exercise, coughing or sneezing, as compared to incontinence associated with a feeling of urgency).
• The stress urinary incontinence is confirmed during physical examination, stress test or urodynamic assessment.
• Moderate to severe incontinence as identified by use of the Sandvik score
• Women should be able to understand the Dutch language both verbally as well as in writing.

Exclusion criteria

• A post voiding bladder volume of more than 100 ml, as determined by bladder catheterisation or ultrasound (Bladderscan®)
• History of anti-incontinence surgery
• Genital prolapse Stage 2 (Ba >0) or more according to the POP-Q classification
• Patients desire for future pregnancy and childbirth
• Co-morbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classification > up to the physician to decide.
• History of recurrent lower urinary tract infection (> 3 times/year)
• History of current major psychiatric illness, as subjectively assessed by the physician
• History of chronic or current neurological disease, as subjectively assessed by the physician

• Poor cognitive function, as subjectively assessed by the physician

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	224
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-03-2021
Application type:	First submission

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
NTR-new	NL9353
Other	METC Isala : METC201114

Study results