Single incision sling versus Bulkamid in treating SUI

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23096

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Stress urinary incontinence

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Isala

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 weeks, 3 months, 1 year

Onderzoeksproduct en/of interventie

• Single incision mid-urethral sling (Altis)
• Urethral injection treatment (Bulkamid)

Contactpersonen

Publiek

Isala
Nienke Osse

0615178217

Wetenschappelijk

Isala
Nienke Osse

0615178217

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	224
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9353
Ander register	METC Isala : METC201114

Resultaten