A trial comparing two different tapes used for surgical treatment of stress urinary incontinence.

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Reducing postoperative pain with a mini-sling.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20238

Bron
NTR

Verkorte titel
TOAST

Aandoening

urinary stress incontinence
mid urethral sling
TVT-O
Ajust

Ondersteuning

Primaire sponsor: University Medical center Utrecht
Overige ondersteuning: Fa Bard

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is the immediate and postoperative pain (up to 6 weeks) after an Ajust® or TVT-O® procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

For the surgical treatment of women with urinary stress incontinence the so-called synthetic midurethral sling has become the Gold-standard. There are two separate ways to place the sling. The first technique is the retropubic approach, the Tension-free Vaginal Tape (TVT®). This technique carries the risk of bladder perforation during surgery. The second approach, the transobturator route (TVT-O®), has an almost zero risk of bladder perforation but is associated with more groin pain as compared to the retropubic TVT®. The groin pain is most likely due to perforation of the external obturator and adductor muscles of the upper leg. The new transobturator device Ajust® does not penetrate these muscles and is therefore in theory less painful as compared to the TVT-O®, with the benefit of reducing the risk of bladder perforation as compared to the retropubic TVT®.

Objective:

Primary Objective: To compare the immediate and postoperative pain (up to 6 weeks) between the Ajust® and TVT-O® procedures.

Secondary Objective(s):

1. Objective cure of the SUI at 6 and 12 months follow up;

2. Subjective cure and improvement of the SUI at 6 and 12 months follow up;

3. Complications during and after the procedures;

4. De novo obstructive or irritative bladder symptoms;

5. Time to return to normal daily activities/work.

Study design:

Randomised controlled trial.

Study population:

Woman between 35 - 80 years of age with urinary stress incontinence.

Intervention:

The TVT-O® device will be compared to the Ajust® device.

Main study parameters/endpoints:

The difference between the Ajust® and TVT-O® procedure in immediate and postoperative pain (up to 6 weeks), complications, obstructive or irritative bladder symptoms, objective and subjective cure, and resuming daily activities.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The burden related to the study is minimal. It mainly consists of the use questionnaires at regular intervals and weekly telephone interviews (up to 6 weeks) of approximately 5-10 minutes. Except for the one year follow-up all other visits are part of the regular care. No additional risks, other than those that are known to be related to any stress incontinence surgery, are expected to be related to the new Ajust® device. The Ajust® device is officially registered in Europe and clinical available.

Doel van het onderzoek

Reducing postoperative pain with a mini-sling.

Onderzoeksopzet

Inclusion 12-18 months.

Onderzoeksproduct en/of interventie

Mid uerthral sling placement (TVT-O or ajust).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Predominant stress incontinence;

2. Stress incontinence is confirmed;

3. Completed conservative therapy;

4. Sandvic index >3;

5. Good knowledge of dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Postvoid residual volume > 100cc;

2. History of anti-incontinence surgery;

3. Prolapse POPQ st 2 or >;

4. Desire for future pregnancy / childbirth;

5. Co-morbidity (ASA 3 or 4);

6. History of recurrent cystitis;

7. Psychiatric illness;

8. Poor cognitive function;

9. Chronic or current neurologic illness.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	145
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2010
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	NL2288
NTR-old	NTR2558
Ander register	METC UMCU : 10-195
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A