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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20238

Source
NTR

Brief title
TOAST

Health condition

urinary stress incontinence
mid urethral sling
TVT-O
Ajust

Sponsors and support

Primary sponsor: University Medical center Utrecht
Source(s) of monetary or material Support: Fa Bard

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Objective cure of the SUI at 6 and 12 months follow up:

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

2. Complications after the procedures;

3. De novo obstructive or irritative bladder symptoms;

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

Study description

Background summary

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.

Study objective

Reducing postoperative pain with a mini-sling.

Study design

Inclusion 12-18 months.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Predominant stress incontinence;

2. Stress incontinence is confirmed;

3. Completed conservative therapy;

4. Sandvic index >3;

5. Good knowledge of dutch language.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	145
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-10-2010
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	NL2288
NTR-old	NTR2558
Other	METC UMCU : 10-195
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A