A randomised controlled trail comparing the TVT-O® with the Ajust® as primary surgical treatment of female stress urinary incontinence.

Published: 25-08-2010
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Objective: Primary Objective: to compare the immediate and postoperative pain (up to 6 weeks) between the Ajust® and TVT-O® proceduresSecondary Objective(s): 1. Objective cure of the SUI at 6 and 12 months follow up2. Subjective cure and improvement...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34244

Source
ToetsingOnline

Brief title
TOAST

Condition

- Genitourinary tract disorders NEC

Synonym
stress urinary incontinence, urinary loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: BARD,Firma BARD

Intervention

Keyword: ajust®, stress urinary incontinence, TVT-O®

Outcome measures

Primary outcome

The difference between the Ajust® and TVT-O® procedure in immediate and

postoperative pain (up to 6 weeks)

Secondary outcome

The difference between the procedures in immediate and postoperative pain (up

to 6 weeks), complications, obstructive or irritative bladder symptoms,

objective and subjective cure, and resuming daily activities.

Study description

Background summary

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 Ajust device will be placed in the same direction as the TVT-O in order to minimize the risk of bladder perforation. Different from the TVT-O is that the needle only pass the obturator foramen. A polypropylene anchor provides fixation. One of the benefits will be that the needle won't penetrate the muscles and is therefore in theory less painful as compared to the TVT-O®.

Study objective

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

Intervention

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

Study burden and risks

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

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Predominant stress urinary incontinence
2. The stress urinary incontinence is confirmed during physical examination, stress test or urodynamic assessment.
3. They have completed conservative treatment for their stress urinary incontinence, pelvic floor muscle training program

Exclusion criteria

1. A post voiding bladder volume of more than 100 ml.
2. History of anti-incontinence surgery
3. Genital prolapse Stage 2 or more according to the POP-Q classification
4. Patients desire for future pregnancy and childbirth
5. Co-morbidity

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2010
Enrollment:	145
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL32171.041.10