The European Study of Altis® Single Incision Sling System for Female Stress Urinary Incontinence;A prospective, post-market, single arm, multicenter comparing baseline data to the 12 and 36 month data in 136 patients with stress urinary incontinence

Published: 30-05-2013
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Primary goal:The cure at 12 monthsSecondary goals:1. Cough Stress Test (HST): objective endpoint2. Question 3 of the UDI-6 questionnaire: subjective endpoint3. Primary endpoint at 6 weeks, 6 months, and 36 months 24maanden4. Reduction of urine loss...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urethral disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON40466

Source
ToetsingOnline

Brief title
EASY-Study

Condition

- Urethral disorders (excl calculi)

Synonym
Stress urine incontinence / urinary loss

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Coloplast,Coloplast manufacturering France

Intervention

Keyword: Stress urinary incontinence, Urethra-slingsystem

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects that meet the criteria of

cure at 12 months.

Healing is defined as negative cough stress test (HST) and NO to question 3 of

the UDI-6 questionnaire: Do you often suffer from urine leakage related to

coughing sneezing or laughing.

It is a composite endpoint of objective and subjective outcome measures.

Secondary outcome

Secondary goals:

1. Cough Stress Test (HST): objective endpoint

2. Question 3 of the UDI-6 questionnaire: subjective endpoint

3. Primary endpoint at 6 weeks, 6 months, and 36 months 24maanden

4. Reduction of urine loss in 24 hours at 6 weeks and 12 months.

5. Postoperative improvement adhv PGI-I questionnaire and patient

satisfaction at every visit

6. Qmax and PVR at 6 weeks and 12 months and the variation compared to

Baseline

7. anesthesia type

8. operation time

9. duration of hospitalization

10. Postoperative pain score using VAS 0-10

11. Device and procedure related adverse events

Study description

Background summary

The surgical treatment of women with stress incontinence is the mid-urethral sling the gold standard.
There are several ways to place the sling.
The first technique is the retropubic approach (TVT ®) with this technique is a complication bladder perforation.
The second approach is the transobturator route (TVT-O ®) here is hardly any risk of bladder perforation causing Horticultural but this technique has a higher risk of groin pain in the compare operation with the TVT ®. Pain in the groin is probably caused by the tape through the muscles of the pelvis and thigh is placed.
The new device Altis ® Single incision sling is in the same direction as the TVT-O ® posted to the risk of bladder perforation to minimize unlike the TVT-O ® is the tape just through the foramen obturatorium placed waabij it using a anchor behind the foramen fixes. A possible advantage is that the needle is not covered by the muscles to the outside have to be carried out. It is expected that the Altis ® SIS will give less pain than the TVT-O ®

Study objective

Primary goal:
The cure at 12 months

Secondary goals:
1. Cough Stress Test (HST): objective endpoint
2. Question 3 of the UDI-6 questionnaire: subjective endpoint
3. Primary endpoint at 6 weeks, 6 months, and 36 months 24maanden
4. Reduction of urine loss in 24 hours at 6 weeks and 12 months.
5. Postoperative improvement adhv PGI-I questionnaire and patient satisfaction at every visit
6. Qmax and PVR at 6 weeks and 12 months and the variation compared to

Baseline
7. anesthesia type
8. operation time
9. duration of hospitalization
10. Postoperative pain score using VAS 0-10
11. Device and procedure related adverse events

Study design

Multi center single arm prospective postmarket study

Intervention

Surgical procedure involving a single incision in witch a mid urethral sling will be placed

Study burden and risks

The tax which the research entails consists of completing the questionnaires, 3 extra visits in the context of the study at 12 months 24 months and 36 months. There is no other risk than the known risks related to the surgical treatment of stress incontinence
The Altis ® Singele Incision System is already available for use in the clinic

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.Pre dominant stress urinary incontinence
2.The stress urinary incontinence is confirmed during physical examination, stresstest or urodynamic assessment

Exclusion criteria

1. Hisstory of anti incontinence surgery
2. A post voiding bladder volume more than 100ml
3. Co-morbidity
4. Desire for future pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	06-01-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Single incision Sling (Altis®)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-05-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-12-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-11-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL42900.075.13