

# 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

Last updated: 24-04-2024

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  
4. Reduction of urine loss...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Urethral disorders (excl calculi)
<b>Study type</b>	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 manufacturing 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 24 maanden
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 waarbij 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 24 maanden
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
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## **Study design**

Multi center single arm prospective postmarket study

## **Intervention**

Surgical procedure involving a single incision in which 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 ® Single Incision System is already available for use in the clinic

## **Contacts**

### **Public**

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NL

### **Scientific**

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NL

## **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, stress test or urodynamic assessment

### Exclusion criteria

1. History 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