PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Safety and Efficacy of Low-elasticity Polyvinylidene Fluoride (DynaMesh®-SIS Soft) Retropubic Tension Free Midurethral Sling in the Treatment of Stress Urinary Incontinence in Women

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study is designed to evaluate the safety and efficacy of low elasticity polyvinylidene fluoride (DynaMesh®-SIS soft) retropubic tension-free midurethral slings in the treatment of stress urinary incontinence in women. Women who are having a retropubic PVDF midurethral sling for urodynamic stress incontinence will be followed up for 24 months to address its efficacy and rate of complications.

Brief Summary in Scientific Language

This study is designed to evaluate the safety and efficacy of low elasticity polyvinylidene fluoride (DynaMesh®-SIS soft) retropubic tension-free midurethral slings in the treatment of stress urinary incontinence (SUI) in women.

Stress urinary incontinence is a common problem, affecting large numbers of women. If conservative measures are ineffective then surgery is offered. Surgery involves a permanent mesh sling being placed, tension free beneath the midurethra. The standard retropubic tension-free vaginal tape (TVT) has been used since 1996 using a polypropylene mesh.(1) The use of permanent mesh in gynaecology has come under scrutiny due to significant complications for women.(2) This year the Medicines and Healthcare Products

Regulatory Agency (MHRA), UK concluded that there is not enough evidence to withdraw mesh from clinical usage.(3)

The sling being studied is DynaMesh®SIS soft, made of polyvinylidene fluoride (PVDF) which has improved biocompatibility with tissues, meaning reduced scar formation and less mesh shrinkage.(4) Each sling is individually woven and and has low elasticity meaning dimensions are maintained under tension, such as with coughing or straining. The technique of retropubic placement of the DynaMesh®SIS soft does not differ from current retropubic TVT placement.

The hypothesis is that the low elasticity polyvinylidene fluoride midurethral sling is non-inferior in both safety and efficacy compared with the safety and efficacy of traditional polypropylene slings, as reported in current literature.

There are eight research centres in three countries, The United Kingdom, Ireland and Germany. The DynaMesh®SIS soft sling is currently in use in four of eight of the research hospitals, Norwich (main research centre), Antrim and Belfast in the UK and in Munich in Germany. It will be introduced in London, Cambridge and Huntingdon in the UK and Dublin in Ireland.

Women with urodynamic stress incontinence who are already assigned to have this retropubic midurethral tape placed for treatment will be recruited prior to their procedure for ongoing follow up. Participants will complete standardised urinary incontinence and quality of life questionnaires prior to their procedure and at 3,6,12, 18 and 24 months by post. Clinical follow up will occur at 3 and 12 months post operatively and as required if any concerns.

Organizational Data

- DRKS-ID: **DRKS00008815**
- Date of Registration in DRKS: **2015/08/11**
- Date of Registration in Partner Registry or other Primary Registry: **2015/03/24**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02407145 (ClinicalTrials.gov)**
- Partner Registry-ID: **2015O+G01M ((Norfolk and Norwich University Hospitals NHS Foundation Trust))**

Health condition or Problem studied

- Free text: **Urinary Stress Incontinence**
- Free text: **Urinary Incontinence,Stress**
- ICD10: **N39.3 - Stress incontinence**

Interventions/Observational Groups

- Arm 1: **Other: 24 month follow up of women with validated questionnaire**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Efficacy of retropubic midurethral PVDF slings assessed by subjective cure rate of retropubic midurethral PVDF slings in treating stress urinary incontinence compared to the reported cure rate for traditional polypropylene retropubic slings.; time frame: 3 to 18 months

Secondary Outcome

- Safety of retropubic midurethral PVDF slings assessed by the rate of

complications of retropubic midurethral PVDF slings, in particular vaginal erosions, compared to those reported in the literature for traditional polypropylene retropubic slings; time frame: 3 to 18 months
- Quality of life assessed by changes in ICIQ-LUTS(qol) questionnaires over the study period; time frame: 3 to 18 months

Countries of recruitment

- DE **Germany**
- IE **Ireland**
- UK **United Kingdom**

Locations of Recruitment

- **Chirurgische Klinik, Munich**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2015/08/31**
- Target Sample Size: **268**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **20 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- women with proven urodynamic stress incontinence in whom a retropubic midurethral sling is appropriate treatment as per the treating urogynaecologist, gynaecologist or urologist

- women who have not had a previous incontinence procedure

- no concomitant prolapse procedure at the time of sling placement

Exclusion criteria

- urodynamic studies negative for stress urinary incontinence

- previous incontinence procedures

- non English/non German speaker depending on study centre

- lack capacity to consent

Addresses

■ **Primary Sponsor**

Norfolk and Norwich University Hospitals NHS Foundation Trust

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Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996;7(2):81-5; discussion 85-6.; 8798092**
- Further trial documents **U.S. FDA Safety Communication: urogynecologic surgical mesh: update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse. July 2011**
- Further trial documents **A summary of the evidence on the benefits and risks of vaginal mesh implants. October 2014. Medicines and Healthcare Products Regulatory Agency, United Kingdom.**
- Further trial documents **Klinge U, Binneboesel M, Kuschel S, Schuessler B. Demands and properties of alloplastic implants for the treatment of stress urinary incontinence. Expert Rev Med Devices. 2007 May;4(3):349-59. Review.; 17488229**

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 4
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.