Trial Description

Title

Prospective multicentric observational study for surgical treatment of stress urinary incontinence with a suburethral polypropylen tape (NEOMEDIC KIM)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Female patients with surgical need to treat stress urinary incontinence will be supplied with the Neomedic KIM tape which is inserted via a vaginal incision. Postoperative adjustion of the tape allows to find the individual necessary tension of the tape.
Compatibility, quality of life and complications are documented perioperatively and after a follow-up of 6 and 12 months.
Open, prospective and multicentre observational study.
Around 200- 250 patients in 8 centers are included.

Brief Summary in Scientific Language

For therapy of female urinary stress incontinence the tension free suburethral tape is an effective treatment, which is the gold standard world-wide. The success rates are reduced in case of risk factors like obesity, mixed incontinence, recurrence and hypotone urethra. A possible complication are bladder emptying problems and in case of insufficient tension of the tape an early recurrence. In these cases an adjustable tape might increase the success rate in a risk collective and reduce the frequency of postoperative bladder emptying problems and early recurrences.

Organizational Data

- DRKS-ID: **DRKS00007614**
- Date of Registration in DRKS: **2014/12/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **125/14 (I) , Ethikkommission der Ärztekammer Schleswig-Holstein (Ethik-Kommission I)**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1164-9662**

Health condition or Problem studied

- ICD10: **N39.3 - Stress incontinence**

Interventions/Observational Groups

- Arm 1: **Patients with a need for surgical treatment of stress urinary incontinence will be supplied with an suburethral tape (TVT technique). In this observational study the NEOMEDIC KIM tape is used. Follow- up after 6 and 12 months.**

Characteristics

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

Primary Outcome

extension of knowledge concerning success rate and follow-up of therapy with an adjustable suburethral tape
Final point: Review of compatibiliy, quality of life and complications after surgical insertion of Neomedic KIM tape suburethral.
Review preoperatively, before discharge and after 6 and 12 months.
Review with clinical examination, ultrasound and questionnaires.
The parameters are: preoperatively: age, weight, height, urogynecological operations in history, intake of spasmolytic drugs, criterions of stress incontinence (Ingelmann- Sundberg, mixed incontinence, hypotone urethra, bladder emptying problems), quality of life, validated incontinence questionnaire ICIQ-SF.
At discharge: follow-up of operation (aquadissection), intra- and postoperative complications, adjustment of tape, pain, cough test, other complaints.

After 6- 12 months: revision of operation, pain, recurrence of stress incontinence, cough test, intake of spasmolytic drug, residual volume, tape erosion, infection at insertion point of tape/suture, satisfaction, question for repeat operation, other complaints, quality of life, validated incontinence questionnaire ICIQ-SF

Secondary Outcome

influence of adjustable tape on subjective complaints, quality of life and satisfaction with the operation
frequency of intra- and postoperative complications (erosion, bladder lesion, hematoma, pain).
Review with clinical examination, ultrasound and questionnaire (incontinence questionnaire ICIQ-SF) preoperatively, before discharge, after 6 and 12 months.

Countries of recruitment

- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- Medical Center **Frauenklinik Preetz, Preetz**
- Medical Center **Frauenklinik, Tettnang**
- Medical Center **Oberhavel Kliniken, Klinik Oranienburg, Frauenklinik, Oranienburg**
- Medical Center **Frauenklinik St. Marien Hospital, Gelsenkirchen**
- Medical Center **Frauenklinik Klinikum Ortenau, Offenburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/01/05**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1) patients with complicated and non- complicated stress incontinence, who need surgical treatment
2) patients from age of 18 years
3) fullfilled family planing
4) cooperation for data collection, therapy and follow-up investigations
5) patient information was delivered and written consent is present
6) urodynamics are obligatory in case of complicated stress incontinence (e.g. previous incontinence operation, neurologic symptoms, mixed incontinence)
7) obligatory single shot antibiotics pre-/ peroperatively

Exclusion criteria

1) pregnancy
2) simultaneous prolapse surgery
3) prolapse of uterus or vagina > POP-Q II
4) known imcompatibility of the implant
5) immobile urethra
6) no previous urodynamic investigation in case of complicated stress incontinence (see inclusion criterion)
7) state after radiation in true pelvis

Addresses

- **Primary Sponsor**

  Neomedic International
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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*