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

Trial Description

Title

BPH-6: A UroLift® System Post Market Multi-Center Randomized Study

Trial Acronym

BPH-6

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to compare the UroLift System Treatment to Transurethral Resection of the Prostate (TURP) in improving a patient's overall quality of life, while evaluating healthcare expenditures associated with each therapy.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00004058**
- Date of Registration in DRKS: **2012/08/01**
- Date of Registration in Partner Registry or other Primary Registry: **2012/02/10**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01533038 (ClinicalTrials.gov)**
- Sponsor-ID: **CP12317 (NeoTract, Inc.)**

Health condition or Problem studied

- Free text: **Benign Prostatic Hyperplasia**
- ICD10: **N40 - Hyperplasia of prostate**

Interventions/Observational Groups

- Arm 1: **Device: UroLift System**
- Arm 2: **Procedure: Transurethral Resection of the Prostate**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

**- Responder Analysis: A Subject is a Responder at the 12 Month Follow-up Time Point if All 6 Thresholds of the BPH-6 Endpoint Are Met; time frame: Month 12;
LUTS: ≥ 30% reduction in IPSS compared to baseline
Recovery Experience: Return to pre-operative activity levels by 1 month
Erectile function: Less than 6-point reduction in SHIM compared to baseline.
Ejaculatory function: Response on MSHQ-EjD that indicates emission of semen. This excludes the response "Could not ejaculate"
Continence: ISI score of 4 points or less at all follow-up time points
Safety: No procedure-related adverse event greater than Grade I on the Clavien-Dindo classification system modified for TURP at any time during procedure or follow up.**

Secondary Outcome

[---]*

Countries of recruitment

- DK **Denmark**
- DE **Germany**
- UK **United Kingdom**

Locations of Recruitment

- **PAN Klinik, Cologne**
- **University Hospital Freiburg, Freiburg**
- **Ludwigs-Maximilians Universität / Klinikum Großhadern, Munich**
- **University Hospital Tuebingen, Tuebingen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/02/27**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **50 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Men >50 years old with moderate-severe BPH

Exclusion criteria

- Size, width of prostate

- Other medical condition or co-morbidity contraindicative for TURP or UroLift

Addresses

- **Primary Sponsor**

  NeoTract, Inc.

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

- **Contact for Scientific Queries**

  University Vita Salute San Raffaele
  Francesco Montorsi, MD

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

- **Contact for Public Queries**

  University Vita Salute San Raffaele
  Francesco Montorsi, MD

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

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 complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

Trial Publications, Results and other documents

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: 7
- 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.