Trial Description

Title

Outcome of transurethral resection of the prostate in patients with glands > 70ccm

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

The Transurethral resection of the prostate (TUR-P) is the most common surgical treatment option of benign prostate enlargement.

For patients with prostatic glands > 70 ccm most clinic perform open adenomectomy. In our clinic we use the TUR-P for every patient regardless the gland volume.

We hypothesise that the TUR-P is a safe treatment option with good long-term outcome for patients with every size of prostatic gland.

Therefor we analyse the clinical course of patients who have been operated approximately 5 years ago and compare the results of patients with prostatic volume < 70 ccm and > 80 ccm.

Besides the analysis of existing data we will reassess the patients with questionnaires, urine flow measurement and ultrasound.

Brief Summary in Scientific Language

Treatment options of BPH are TUR-P, open adenomectomy and different laser methods.

**For gland sizes > 70 ccm most clinics still prefere the open adenomectomy.
We perform the TUR-P in all of our patients (with gland sizes up to 150 - 200 ccm). This is possible due to the use of a suprapubic suction system and consequent low pressure resection.**

This study will investigate the clinical course of patients during the operation and after 5 years.

Organizational Data

- DRKS-ID: **DRKS00006527**
- Date of Registration in DRKS: **2014/07/25**

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- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **309/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1159-5422**

Health condition or Problem studied

- ICD10: **N40 - Hyperplasia of prostate**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Outcome Analysis 5 years after TUR-P with questionnaires, sonographic estimation of post-void residual urine and peak flow Analysis. Comparison of results of patients with prostatic Gland < and > 70 ccm</style>

Characteristics

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

Primary Outcome

Comparison of perioperative and Long-term outcome (perioperative: blood transfusion rate, bleeding, revision, urinary retention, other complications. Long-term outcome: IPSS (International Prostate Symptom Score), ICIQ (International Consultation on Incontinence Questionnaire), IIEF (International Index of Erectile Function), post-void residual urine, Peak flow, Re-operation).
Comparison of the results for patients with prostatic gland size < and > 70 ccm

Secondary Outcome

Comparison of complications

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Freiburg, Klinik für Urologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/08/01**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

TUR-P in our clinic between 2009 and 2011

Exclusion criteria

Denial of participation by individual

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

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

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.