Trial Description

Title

Evaluation of functional and psychsexual results after surgical penile curvature correction (PCC) based on patient reported outcomes (PRO)

Trial Acronym

PRO-PCC

URL of the trial

http://www.uniklinik-freiburg.de/urologie

Brief Summary in Lay Language

Evaluation of functional and psychosexual results after surgical penile curvature correction based on patient reported outcomes (questionnaires). To date, results of a penis straightening surgery were clinically proven with objective measurable data. The aim of this study is to compare different surgical techniques for correction of penile curvature by patient-based questionnaires. The forms are going to be collected from multiple international centers and analyzed statistically. In the study, about 200 patients are going to be enrolled. The evaluation of the questionnaires is anonymous. The results allow a comparison of different surgical procedures and their impact on subjective patient-centered functional aspects against the functionally measurable outcome.

Brief Summary in Scientific Language

To date results after surgical interventions usually are documented as clinical reported outcomes (CRO, measurements of functional outcome). It is the aim of this study to compare the results of different surgical techniques for correction of penile curvatures by means of patient reported outcomes (PRO). In a multicentre retrospective study data of validated questionnaires for erectile function (IIEF-5) and treatment-related patient satisfaction (Freiburg Index of Patient Satisfaction FIPS), as well as the personal evaluation of the cosmetic and functional results by an open questionnaire, will be aquired and compared between different surgical techniques.
The study will include 200 patients (approx. 50 from Freiburg). Evaluation of the questionnaires will be performed de-personalized.
Results of the study will be compared to existing data based on CROs. This will allow for a comparison of different surgical techniques from a subjective standpoint of the patient as compared to objective functional outcomes.

Organizational Data

- DRKS-ID: **DRKS00003330**
- Date of Registration in DRKS: **2011/11/21**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **421/11 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **N48.6 - Induratio penis plastica**
- Free text: **congenital penile curvature**

Interventions/Observational Groups

- Arm 1: **Non interventional study: All patients afer surgical treatment of a congenital penile curvature (Nesbit technique). Patients need to fill out study forms (questionnaires) and return them to the study center. This ends the patient's active participation in the study.**
- Arm 2: **Non interventional study: All patients afer surgical treatment of a congenital penile curvature (Dermagraft technique). Patients need to fill out study forms (questionnaires) and return them to the study center. This ends the patient's active participation in the study.**
- Arm 3: **Non interventional study: All patients afer surgical treatment of a congenital penile curvature (Egydio technique). Patients need to fill out study forms (questionnaires) and return them to the study center. This ends the patient's active participation in the study.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**

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Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Statistical analysis of the psychometric and functional results of the study. (Evaluation of the study questionnaires)

Secondary Outcome

no secondary outcome

Countries of recruitment

- DE **Germany**
- AT **Austria**
- BR **Brazil**
- US **United States**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/01**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/12/01**

Target Sample Size: **200**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **16 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

All patients, who have received a surgical penile curvature treatment in the last 4 years at one of the participating centers.

Exclusion criteria

Patients under 16 years, dementia or addiction, not incapacitated for other reasons

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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 complete, follow-up complete**

- Study Closing (LPLV): **2014/10/01**

Trial Publications, Results and other documents

- Further trial documents **Literaturliste**
- Abstract **International multicentre psychometric evaluation of patient-reported outcome data for the treatment of Peyronie's disease**

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