A prospective Multicenter Randomized Study Comparing Photoselective Vaporization of the Prostate with the GreenLight XPS Laser System and Transurethral resection of the Prostate for Treatment of benign Prostatis Hyperplasia

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON36344

Source
ToetsingOnline

Brief title
GreenLight XPS vs TURP Randomized Study

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
Benign Prostate Hyperplasia

Research involving
Human

Sponsors and support

Primary sponsor: American Medical Systems
Source(s) of monetary or material Support: AMS

Intervention

Keyword: BPH, GreenLight, Randomized, XPS

Outcome measures

Primary outcome

To demonstrate that BPH symptoms after PVP are not worse when compared to TURP

at 6 months post procedure measured via international prostate symptom score

(IPSS) for the treatment of BPH.

Secondary outcome

1. To compare the complication-free rate between PVP and TURP

2. To compare prostate volume post treatment for PVP and TURP

3. To compare functional status of PVP and TURP via maximum urinary flow rate

(Qmax)

4. To compare immediate post intervention outcomes of PVP and TURP

• Short Form Health Survey (SF-36) Acute at 3-week visit

• Length of stay

5. To compare health status of PVP and TURP

• International prostate symptom score (IPSS)

• BPH Impact Index (BII)

• Overactive Bladder Questionnaire (OABq)

• SF-36 Acute

• EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D)

6. To compare tolerability of PVP and TURP

• International Index of Erectile Function (IIEF)

• ICIQ-SF International Consultation on Incontinence Questionnaire Short Form

7. To compare subject satisfaction of PVP and TURP

• Subject satisfaction questionnaire

8. To compare rate of retreatment of PVP and TURP

Study description

Background summary

Limited published literature and randomized data are available to demonstrate the differences between PVP and TURP and suggest additional randomized studies comparing PVP and TURP are needed to demonstrate efficacy, safety and health economic outcomes.1,2 This study is designed to understand these differences and the impact to patient-reported outcomes, health economics and overall safety.

Study objective

The study will compare procedural and post procedural outcomes for photoselective vaporization of the prostate (PVP) and transurethral resection of the prostate (TURP). The study requires use of the CE marked GreenLight XPS* Laser System (GreenLight XPS) or a CE marked monopolar or bipolar loop TURP system for the treatment of benign prostatic hyperplasia (BPH). The purpose of the study is to demonstrate that PVP is not inferior to TURP.

Study design

This is a randomized, prospective, multicenter study design to be conducted at up to 25 centers in Europe. The primary endpoint will be measured at 6 months and subjects will be followed out to 2 years to collect long-term clinical data.
Approximately 252 subjects will be enrolled in order to achieve a minimum of 188 subjects with 6 month follow-up IPSS data. A conservative attrition rate of 25% was used to account for subjects enrolled and not receiving treatment or who are missing 6-month follow-up IPSS data. The goal is for each study center

is to enroll 1 subject per month with a maximum of 38 subjects enrolled per center; additional subjects may only be enrolled with written preapproval from the sponsor.
Individual subjects will be exited upon completion of the 2-year follow-up visit. The total study duration is estimated to be 4 years from time of first enrollment through final subject completing a 2-year follow-up visit.

Intervention

Subjects will be randomized to be treated either receiving PVP or TURP therapy. They will be followed for the duration of 2 years

Study burden and risks

Both PVP and TURP procedures carry the CE mark and have similar risk profiles. There are no additional risks associated with participation in the study. For risks associated with surgical treatment of BPH please see the protocol, chapter 10.2

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The patient is candidate for desobstructive surgery of the prostate due to symptomatic BPH by TURP or PVP
The IPSS score is > 12
Qmax < 15 ml/sec
Prostate Volume < 100 cc

Exclusion criteria

Life expectancy < 2 years
Active Urinary Tract Infection
Prostatitis
Neurogenic bladder
Diagnosis prostate carcinoma

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-09-2011
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34977.091.10