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A Randomised Study Comparing Laser Therapy (Greenlight XPS™ Laser System) Versus Conventional Surgery (Transurethral Resection of the Prostate [TURP]) for the Treatment of Benign Prostatic Hyperplasia

Submission date	Recruitment status	[_] Prospectively registered
11/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/03/2018	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

PE1006

Study information

Scientific Title
A Prospective Multicentre Randomised Study Comparing Photoselective Vaporisation of the Prostate with the GreenLight XPS™ Laser System and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Hyperplasia

Acronym
Greenlight XPS vs. TURP

Study objectives
To demonstrate that Benign Prostatic Hyperplasia (BPH) symptoms after Photoselective Vaporisation (PVP) are not worse when compared to Transurethral Resection of the Prostate (TURP) at 6 months post procedure measured via international prostate symptom score (IPSS) for the treatment of BPH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee approval to be submitted

Primary study design
Interventional

Study design
Prospective multicentre randomised active controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Benign Prostatic Hyperplasia (BPH)

Interventions
Patients will be randomised to receive either
1. GreenLight XPS 532 nm Laser System with MoXy™ laser fiber
2. Monopolar or bipolar loop TURP systems carrying the CE mark

Intervention Type
Procedure/Surgery

Primary outcome(s)
Severity of BPH symptoms 6 months post procedure measured by international prostate symptom score (IPSS)

Key secondary outcome(s)

1. Complication-free rates at 3 weeks post-procedure
2. Prostate volume (via TRUS or abdominal ultrasonography) as reported on the case report forms at baseline and 6-month follow-up visit
3. Functional status, measured by maximum urinary flow rate (Qmax) at 3, 6, 12, and 24-month follow-up visits (The proportion of subjects with a Qmax of 15ml/s or greater will be noted)
4. Immediate post intervention outcomes of PVP and TURP
4.1. Short Form Health Survey (SF-36) Acute at baseline and 3-week visit
4.2 Length of stay
5. Health status, measured at 3, 6, 12, and 24 month follow-up visit
5.1. International prostate symptom score (IPSS)
5.2. BPH Impact Index (BII)
5.3. Over-active Bladder Questionnaire (OABq)
5.4. SF-36 Acute
5.5. EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D)
6. Tolerability, measured at 6, 12 and 24 month follow-up visit
6.1. International Index of Erectile Function (IIEF)
6.2. International Consultation on Incontinence Questionnaire Short Form
7. Subject satisfaction, measured at end of study
8. Rate of re-treatment, measured at end of study

Completion date
12/01/2014

Eligibility

Key inclusion criteria
1. Subject has provided informed consent
2. Subject has diagnosis of benign prostatic hyperplasia
3. Subject is willing to be randomised
4. Clinical investigator has documented in the subjects medical record that in his/her judgment the subject is a surgical candidate for either the PVP or the TURP procedure and may be randomised into either arm
5. Subject is greater than or equal to 40 years of age
6. Subject has an International Prostate Symptom Score (IPSS) score greater than or equal to 12 measured at the baseline visit
7. Subject has medical record documentation of a maximum urinary flow rate (Qmax) less than 15ml/s (If uroflow testing documentation is available within 90 days prior to the informed consent date, and the sample is greater than or equal to 125ml, and the Qmax is less than 15ml /s it may be used for the inclusion/exclusion criteria)
8. Subject has medical record documentation of a prostate volume of less than or equal to 100g by transrectal ultrasound (TRUS) or abdominal ultrasound (If TRUS or abdominal ultrasound testing documentation is available within the 180 days prior to the informed consent date and the prostate volume is less than or equal to 100g, it may be used for the inclusion/exclusion criteria)
9. Subject is classified as American Society of Anesthesiologist (ASA) I, II or III
10. Subject has a serum creatinine less than 1.8 mg/dl measured after the date of the informed consent and prior to the surgical procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subject has a life expectancy of less than 2 years
2. Subject is currently enrolled in, or plans to enroll in, any concurrent drug or device study unless pre-approved by the sponsor
3. Subject has an active infection (eg, urinary tract infection or prostatitis)
4. Subject has a history of 2 or more urinary tract infections in the 365 days prior to the informed consent date
5. Subject has a diagnosis of chronic bacterial prostatitis or chronic pelvic pain syndrome (eg, non-bacterial chronic prostatitis)
6. Subject has been diagnosed with a urethral stricture or bladder neck contracture within the 180 days prior to the informed consent date
7. Subject has been diagnosed with 2 or more urethral strictures and/or bladder neck contractures within the 5 years prior to the informed consent date
8. Subject has a neurogenic bladder or other neurological disorder that would impact bladder function (eg, multiple sclerosis, Parkinsons disease, spinal cord injuries)
9. Subject has a diagnosis of diabetic cystopathy
10. Subject has history of lower urinary tract surgery (eg, urinary diversion, artificial urinary sphincter, penile prosthesis)
11. Subject has diagnosis of stress urinary incontinence that requires treatment or daily pad /device use
12. Subject has a history of intermittent self catheterisation within the 180 days prior to the informed consent date
13. Subject has current diagnosis of bladder stones
14. Subject has diagnosis of prostate cancer
15. Subject has a history of T1 or CIS bladder cancer
16. Subject has damage to external urinary sphincter
17. Subject has a medical contraindication for undergoing either TURP or PVP surgery (eg, infection, coagulopathy or significant cardiac or other medical risk factors for surgery)
18. Subject has a disorder of the coagulation cascade (eg, haemophilia) or disorders that affect platelet count or function (eg, Von Willebrands disease) that would put the subject at risk for intraoperative or postoperative bleeding
19. Subject is unable to discontinue anticoagulant and antiplatelet therapy preoperatively (3-5 days)
20. Subject has had an acute myocardial infarction, open heart surgery or cardiac arrest less than 180 days prior to the date of informed consent
21. Subject is immunocompromised (eg, organ transplant, leukaemia)

Date of first enrolment

12/01/2010

Date of final enrolment
12/01/2014

Locations

Countries of recruitment
United Kingdom

Wales

Germany

Netherlands

Study participating centre
Princess of Wales Hospital
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Sponsor information

Organisation
American Medical Systems, Inc (USA)

ROR
https://ror.org/0385es521

Funder(s)

Funder type
Industry

Funder Name
American Medical Systems, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration