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Transurethral high power (80W) potassium-titanyl-phosphase (KTP) laser vapourisation of the prostate compared with holmium laser ablation of the prostate: a single-centre randomised controlled trial in patients with obst. benign prostatic hyperplasia

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 07/10/2014	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0355178146

Study information

Scientific Title

Study objectives
To determine which of the currently used energy delivery systems in laser prostatectomy provides for the most durable clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Prostatectomy

Interventions
Patients will be invited to participate in the study from the out-patient clinic at the time a decision for surgical intervention has been made. They will have 2-3 weeks to consider whether or not they wish to participate and those electing to join the study will be asked to contact the Clinical Nurse Specialist for formal enrolment and randomization. All patients will be given appropriate information leaflets outlining the aims of the study. Patients electing to join the study will not undergo any further or additional investigations over and above that which is currently regarded as standard or routine practice within the department. The only variable they will submit themselves to is the formal randomization to a particular treatment arm.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Improvements in flow rates and a reduction in IPSS scores

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2005

Completion date
01/05/2007

Eligibility

Key inclusion criteria
All patients will undergo routine assessment to include uroflowmetry, prostate size assessment, PSA testing and an IPSS score. Those between the ages of 55-75 and have Qmax flow rates of <15 ml/sec and an IPSS score of > 12 (moderate-severe LUTS) and have PSA measurements within the normal range will be eligible for the study. Patients with prostate volumes of between 40-120 cc will be deemed suitable for laser ablation surgery.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
80

Key exclusion criteria
Patients with prostate volumes of greater than 120 cc may require open surgery and those with prostate volumes of < 40 cc may simply require bladder neck incision and are therefore exclusion criteria. Patients presenting with chronic urinary retention will be excluded from the study. These patients may have atonic bladders and voiding difficulties following the procedure may be more difficult to interpret for the purposes of the study.

Date of first enrolment
01/11/2005

Date of final enrolment

01/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mid Essex Hospital Services NHS Trust (BH)
Chelmsford
United Kingdom
CM1 7ET

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Sponsor details
Department of Health
Richmond House
79 Whitehall
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SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name

Mid Essex Hospital Services NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration