ISRCTN16583435 https://doi.org/10.1186/ISRCTN16583435

A prospective, randomised, double-blinded study to compare bipolar transurethral resection of the prostate (bipolar TURP) versus monopolar transurethral resection of the prostate (monopolar TURP) in terms of safety and efficacy

Submission date
21/07/2006

Recruitment status
No longer recruiting

Registration date
21/07/2006

Overall study status
Completed

Last Edited
19/09/2007

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.turp.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
TURP

Study objectives
Bipolar devices will minimise the disadvantages of the monopolar device such as the risk of electrolyte disturbances by using saline irrigation, bleeding and the risk of nervous stimulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
A prospective, randomised, double-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions

Patients will be randomised into either:
Group A: who will undergo a bipolar TURP
Group B: who will undergo a monopolar TURP

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Safety bipolar TURP compared with monoploar TURP by means of transurethral resection (TUR) syndrome
2. Blood loss
3. Number and severity of adverse events

Secondary outcome measures
1. Efficacy of bipolar TURP compared with monopolar TURP by means of IPSS or quality of life (QoL) scores
2. International index of erectile function (IIEF) score
3. Qmax
4. Cutting rate
5. Length of catherisation
6. Length of hospital stay
7. Length of operation
8. Impact on prostate specific antigen (PSA) level
9. Number of strictures

Overall study start date
01/07/2006

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Candidates for transurethral resection of the prostate (TURP)
2. Qmax less than 16 ml/sec
3. International Prostate Symptom Score (IPSS) score greater than 14
4. Voided volume greater than 125
5. Patients in retention with an indwelling catheter or intermittent catheterisation
6. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
94

Key exclusion criteria
1. If patient is suspected to be suffering from prostate cancer
2. Prior prostate surgery, including minimal invasive therapies
3. Active urinary tract infection
4. Known or suspected neurogenic decompensated bladder (postvoid residual urine volume [PVR] greater than 400ml/sec) or compensated detrusor function
5. Immunosuppression; using prednisone
6. Known or suspected malignant disease affecting the bladder or lower urinary tract
7. 5-alpha-reductase inhibitor within the last three months before baseline
8. Alpha-blockers within the last six weeks before baseline
9. Specific severe heart disease in whom anti-coagulant therapy might jeopardize treatment outcome

Date of first enrolment
01/07/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC), Department of Urology (The Netherlands)

Sponsor details

P.O. Box 22660
Amsterdam
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Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Karl Storz (UK)

Funder Name
Academic Medical Center (AMC) (The Netherlands) - Department of Urology

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