ISRCTN78922760 https://doi.org/10.1186/ISRCTN78922760

Early Clinical outcome of Modified retropubic Versus Transvesical prostatectomy in Management of Benign prostatic hyperplasia: a Randomised Clinical Trial

Submission date
20/08/2007

Recruitment status
No longer recruiting

Registration date
10/07/2008

Overall study status
Completed

Last Edited
11/07/2008

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001

Study information

Scientific Title

Acronym
ECMVTMB: RCT

Study objectives
There is no clinical advantage of modified retropubic prostatectomy over transvesical prostatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research and Ethics Committee of the Faculty of Medicine, Makerere University. Date of approval: 30/07/2007
2. The Mulago National Referral Hospital Research and Ethics Committee. Date of approval: 30 /07/2007

Study design
Non-blinded, 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
Benign prostatic hyperplasia

Interventions
1. Modified retropubic prostatectomy
2. Transvesical prostatectomy

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood loss determined by haemoglobin and haematocrit levels on the third post operative day

Secondary outcome measures
1. Wound sepsis following surgery
2. Rate of return to operating theatre for clot retention

Overall study start date
01/08/2007

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Patients admitted between August 2007 and March 2008 with diagnosis of Benign Prostatic Hyperplasia (BPH)
2. Haemoglobin level of 10 g/dL or more
3. Haematocrit of more than 30%

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
68

Key exclusion criteria
1. Suspected prostatic carcinoma
2. Renal failure
3. Cardiac disease
4. Abnormal bleeding tendencies

Date of first enrolment
01/08/2007

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
Uganda

Study participating centre
Department of Surgery
Kampala
Uganda
256

Sponsor information

Organisation
Mulago Hospital (Uganda)

Sponsor details
Po Box 7051
Kampala
Uganda
256
-

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rhp5f96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mulago Hospital (Uganda)

Funder Name
Resources of Investigator as part of Masters' thesis in surgery

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