

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	<input type="checkbox"/> Prospectively registered
Registration date 10/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration