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

Submission date	Recruitment status	Prospectively registered
20/08/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
10/07/2008	Completed	Results
Last Edited	Condition category	Individual participant data
11/07/2008	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

Contact name

Dr Masaba Joseph Benon

Contact details

Department of Surgery Mulago Hospital Po Box 7051 Kampala Uganda 256 +256 77536089 jmasaba@gmail.com

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

256

Study participating centre
Department of Surgery
Kampala
Uganda

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration