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Effect of warm intravenous and irrigating fluids on body temperature during transurethral resection of the prostate gland

Submission date	Recruitment status	[_] Prospectively registered
20/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2021	Urological and Genital Diseases	

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
TURP/WARM 001

Study information

Scientific Title
Effect of warm intravenous and irrigating fluids on body temperature during transurethral resection of the prostate gland

Study objectives
Transurethral resection of the prostate gland with irrigation and intravenous fluids at room temperature as is currently performed often leads to a drop in the core body temperature with all the possible consequences of hypothermia. Studies have shown that with the use of isothermic irrigation fluids, the drop in the core body temperature is less but still occured in some patients. My hypothesis is that if the intravenous fluid is also isothermic before delivery into the patient along with isothermic irrigation fluid, the core body temperature of the patients SHOULD NOT drop during transurethral resection of the prostate gland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the University of Ibadan (UI)/University College Hospital (UCH) Institutional Review Committee on the 16th August 2007 (ref: UI/IRC/07/0007).

The patients will be fully informed of the study and their written informed consent obtained. There will be NO penalty for refusal to consent.

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
Benign Prostatic Hyperplasia (BPH)

Interventions

Allocation of patients to one of three study groups will be by the picking of a ballot by the patient from a non-transparent jar containing prelabelled squeezed slips containing the group to which the patient will be assigned.

Intervention: TURP using isothermic intravenous and isothermic irrigation fluids

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Hypothermia will NOT occur in the study group.

Secondary outcome measures
The patients will be more comfortable, have less morbidity and have a shorter hospital stay.

Overall study start date
01/01/2001

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Patients with benign prostatic hyperplasia who have obstructive symptoms and are already scheduled to have Transurethral Resection of their Prostate gland (TURP).

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40 in each of three groups

Total final enrolment
120

Key exclusion criteria
Patients with co-morbid conditions such as:
1. Diabetes mellitus
2. Inguinal hernia
3. Vesical calculi

4. Asthma
5. Axial skeletal or hip deformities which interfered with Lloyd Davis positioning
6. Recent cerebrovascular accidents

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Nigeria

Study participating centre
Urology Division
Ibadan
Nigeria
PMB 5116

Sponsor information

Organisation
Individual sponsor (Nigeria)

Sponsor details
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded trial (Nigeria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/09/2007	29/10/2021	Yes	No