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Riyadh benign prostatic hyperplasia (BPH) protocol

Submission date	Recruitment status	[_] Prospectively registered
23/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2008	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Prospective randomised placebo-controlled double-blind crossover trial in using anti-cholinergics with alpha blockers for the treatment of benign prostatic hyperplasia (BPH) in newly diagnosed patients

Study objectives
Anti-cholinergics might improve symptomatic benign prostatic hyperplasia (BPH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the Ethical Committee of the Continuous Medical Research Centre at King Khaled University Hospital in late 2007.

Study design
Prospective randomised placebo-controlled double-blinded crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Benign prostatic hyperplasia

Interventions
All patients will have the following investigations at the recruitment visit: prostate specific antigen (PSA), peak urinary flow rate, post-voiding urine volume, ultrasound for the prostate, kidneys and the bladder with the ditrusal wall thickness, urine analysis, digital rectal exam, the symptoms are more voiding or imitative in nature creatinine level and International Prostatic Symptoms Score (IPSS).

1. Anti-cholinergic group: the patients in this group should receive alpha-blockers (tamsulosin) 0.4 mg orally (PO) once daily (OD) and anti-cholinergic (tolterodine) 2 mg PO twice daily (BID) for eight weeks
2. Control group: the patients in this group should receive alpha-blockers (tamsulosin) 0.4 mg PO OD and placebo tablet PO BID for eight weeks.

The patients will then be crossed over for another four weeks. All of them will be followed up throughout the study.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Alpha blocker (tamsulosin), anti-cholinergic (tolterodine)

Primary outcome measure
Symptoms measured by:
1. The International Prostatic Symptoms Score (IPSS)
2. Peak urinary flow rate (Q max)

All outcomes will be assessed at visit one (zero time), visit two (eight weeks), visit three (one week from the last visit for wash out) and visit four (final visit at sixteen weeks).

Secondary outcome measures
1. Post voiding urine volume (PVR)
2. Ultrasound (optional)

All outcomes will be assessed at visit one (zero time), visit two (eight weeks), visit three (one week from the last visit for wash out) and visit four (final visit at sixteen weeks).

Overall study start date
01/04/2008

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Male patients; no specific age group but for the condition most patients will be aged 50 years and older
2. Naive patients with BPH
3. Have an International Prostate Symptom Score (IPSS) more than seven
4. Must be living in Riyadh city; patients from the peripheries will be excluded
5. Patients who are already on alpha blockers can be included after a washout period of two weeks

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
260 patients

Key exclusion criteria
1. Patients with renal failure
2. Acute angle glaucoma
3. Arrythmias (will be excluded by the past medical history and the current cardiac medication)

Date of first enrolment
01/04/2008

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
P.O.Box 5439
Riyadh
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11422

Sponsor information

Organisation
The Continuous Medical Research Centre at King Khaled University Hospital (Saudi Arabia)

Sponsor details
College of Medicine
University Hospital
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11411

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046gga527

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Continuous Medical Research Centre at King Khaled University Hospital (Saudi Arabia)

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