ISRCTN74130527 https://doi.org/10.1186/ISRCTN74130527

# 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

**Contact name**
Dr Abdulaziz Al Thunayan

**Contact details**
P.O.Box 5439
Riyadh
Saudi Arabia
11422

## 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
Saudi Arabia
11422

## Sponsor information

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

### Sponsor details
College of Medicine
University Hospital
P.O. Box 245
Riyadh
Saudi Arabia
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