

# Riyadh benign prostatic hyperplasia (BPH) protocol

<b>Submission date</b> 23/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/07/2008	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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 detrusor wall thickness, urine analysis, digital rectal exam, the symptoms are more voiding or irritative 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(s)**

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).

### **Key secondary outcome(s)**

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).

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Male

### **Key exclusion criteria**

1. Patients with renal failure
2. Acute angle glaucoma
3. Arrhythmias (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)

### 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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration