

# Effect of alfuzosin hydrochloride on female primary bladder neck obstruction

<b>Submission date</b> 01/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/05/2008	<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**  
Effect of alpha-1 blocker alfuzosin hydrochloride on female primary bladder neck obstruction

**Study objectives**

To assess the effect of the selective alpha-1 blocker alfuzosin hydrochloride on urodynamic and quality of life issues of female patients with functional bladder outlet obstruction (BOO) and especially primary bladder neck obstruction (PBNO).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

At the time of recruitment for this trial (2000) no formal approval was required for a phase IV trial. Patients were informed orally and informed consent was required.

### **Study design**

Observational, case-control prospective study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Female primary bladder neck obstruction (PBNO)

### **Interventions**

Pre-treatment:

1. Urodynamic study including free flow, cystometry, pressure flow study and profilometry, and
2. Bother Score questionnaire

Post-treatment:

The same as pre-treatment plus a question about the Global Assessment of the treatment result.

Treatment:

The dosage of the alfuzosin hydrochloride was 5 mg twice daily for eight weeks. Patients were followed up for eight weeks.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Alfuzosin hydrochloride

### **Primary outcome(s)**

Urodynamic parameters related with obstruction (voiding phase). Primary and secondary outcomes were measured only at the eight-week visit (study closure).

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

1. Measurement of Bother Score Index
2. Global Assessment of Quality of Life
3. Urodynamic parameters related with storage phase

Primary and secondary outcomes were measured only at the 8-week visit (study closure).

**Completion date**

30/05/2008

## Eligibility

**Key inclusion criteria**

1. Female patients older than 18 years old
2. Primary bladder neck obstruction

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Mechanical causes of obstruction
2. Neurological disorders of micturition
3. Hypotension

**Date of first enrolment**

01/02/2000

**Date of final enrolment**

30/05/2008

## Locations

**Countries of recruitment**

Greece

**Study participating centre**

**Papdiamantopoulou 38 str**  
Patra  
Greece  
26225

## **Sponsor information**

### **Organisation**

University Hospital of Patras (Greece)

### **ROR**

<https://ror.org/03c3d1v10>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

University Hospital of Patras (Greece)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration