

Effect of alfuzosin hydrochloride on female primary bladder neck obstruction

Submission date 01/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/05/2008	Condition category Urological and Genital Diseases	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Case-control study

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

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 measure

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

Secondary outcome measures

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).

Overall study start date

01/02/2000

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

25

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

Papadiamantopoulou 38 str

Patra

Greece

26225

Sponsor information

Organisation

University Hospital of Patras (Greece)

Sponsor details

Department of Urology

Rio-Patra

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anathan@upatras.gr

Sponsor type

Hospital/treatment centre

Website

<http://www.upatras.gr/>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital of Patras (Greece)

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