ISRCTN40295045 https://doi.org/10.1186/ISRCTN40295045

Effect of alfuzosin hydrochloride on female primary bladder neck obstruction

Submission date	Recruitment status	[_] Prospectively registered
01/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2008	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
Prof Anastasios Athanasopoulos

Contact details
Papadiamantopoulou 38 str
Patra
Greece
26225
+30 2610 994668
tassos_athan@hotmail.com

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
Patra
Greece
26500
+30 2610 999385
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