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A randomised, placebo controlled study of alfuzosin in patients undergoing trial without catheter following admission with acute urinary retention

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 21/02/2020	**Condition category** Signs and Symptoms	

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

N0050072990

Study information

Scientific Title
A randomised, placebo controlled study of alfuzosin in patients undergoing trial without catheter following admission with acute urinary retention

Study objectives
To evaluate the role of an alpha-1 adrenoceptor antagonist in the treatment of acute urinary retention. To test the hypothesis that oral alfuzosin will increase the proportion of men in acute urinary retention who void after trial without catheter (AVR).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo-controlled study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Acute urinary retention

Interventions
Randomised, placebo-controlled study at two centres. The aim of the study is to evaluate the effectiveness of alpha-adrergic blocker alfuzosin SR 5 mg given to patients in acute urinary retention prior to trial without catheter (TWOC). If successful it would reduce the number of operative treatments for patients with bladder outlet obstruction due to benign prostatic hyperplasia (BPH).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Alfuzosin

Primary outcome measure
Successful outcome will be measured in terms of spontaneous voiding

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

Completion date
31/12/2000

Eligibility

Key inclusion criteria
Patients with acute urinary retention who meet inclusion criteria

Participant type(s)
Patient

Age group
Not Specified

Sex
Male

Target number of participants
Added 18/03/2010: 81

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Luke's Hospital
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Industry

Funder Name
Lorex Synthelabo Ltd (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2002		Yes	No