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Oral desmopressin for treatment of adults with overactive bladder syndrome

Submission date	Recruitment status	[_] Prospectively registered
05/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2011	Urological and Genital Diseases	

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
QLK3-CT-2001-00987

Study information

Scientific Title

Acronym
ACTION

Study objectives
Overactive bladder syndrome (OAB) is a symptom complex consisting of urgency, urgency incontinence (UUI), frequency and nocturia. This study looked at whether oral desmopressin, by decreasing urine production by the kidneys, would prolong bladder filling time thereby increasing the time to reach maximum capacity, thus reducing Overactive Bladder (OAB) symptoms, and providing an alternative method of treatment to OAB sufferers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval by the Southmead Local Ethics Research Committee was recieved 23/01/2004.

Study design
Two-week, multi-national, multi-centre, phase IIb, double blind, prospective, randomised, cross-over, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Overactive bladder syndrome (OAB)

Interventions
0.2 mg oral desmopressin tablets versus placebo.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
1. Evaluation of effectiveness of desmopressin in increasing the time to first unwanted event, in patients with overactive bladder, in the first eight hours of the day, following treatment.
2. Evaluation of the effect of desmopressin on quality of life in patients with overactive bladder syndrome using the International Confrontation on Incontinence (ICI) OAB short form questionnaire.

Secondary outcome measures
Evaluation of effectiveness of desmopressin by decreasing the average number of unwanted events (micturitions, incontinence episodes, urgency episode), during the first eight hours of the day, following treatment.

Overall study start date
03/05/2004

Completion date
14/07/2005

Eligibility

Key inclusion criteria
Male and female patients 18 years of age or older with overactive bladder syndrome if they have an average of four or more voids in the first eight hours of the day (excluding the first void in the morning) and/or more than one incontinence episode in the first eight hours of the day during the seven days screening period.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Consistent residual volume >150 ml
2. Abnormal levels of serum/plasma sodium
3. Newly started Benign Prostatic Hypertrophy (BPH) medical/surgical treatment
4. Diabetes insipidus/primary polydipsia
5. Multiple sclerosis

6. Stress urinary incontinence
7. Pelvic organ prolapse

Date of first enrolment
03/05/2004

Date of final enrolment
14/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Urological Institute
Bristol
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Sponsor information

Organisation
Bristol Urological Institute (UK)

Sponsor details
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Sponsor type
University/education

Website
www.bui.ac.uk

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
European Union (Belgium) - Grant (ref: QLK3-CT-2001-00987)

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	01/06/2009		Yes	No