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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

Protocol serial number
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.

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
Bristol Urological Institute
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Bristol Urological Institute (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

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