A Multicentre, Placebo Controlled, Randomised, Double-blind, Dose Ranging Study of SVT-40776 0.05 mg, 0.1 mg, 0.2 mg, Tolterodine 4 mg and Placebo Daily Doses for 4 Weeks in Patients Suffering from Overactive Bladder Syndrome

Published: 12-06-2006
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To evaluate the dose-response relationship of SVT-404776 on efficacy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON29948

Source
ToetsingOnline

Brief title
SVT-40776

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
urine urgency ; urinate too frequent

Research involving
Human

Sponsors and support

Primary sponsor: Salvat Laboratorios
Source(s) of monetary or material Support: industrie zoals opgegeven bij vraag B6

Intervention

Keyword: OAB, overactive bladder syndrome

Outcome measures

Primary outcome

The change in the number of micturitions per 24 hours from baseline to the end

of the double-blind treatment period.

Secondary outcome

Number of urge incontinence episodes, number of urgency (without incontinence)

episodes, number of incontinence episodes, number of voids (micturitions plus

incontinence episodes), number of urgency episodes, number of nocturia

episodes, number of continent days and volume of urine passed per void.

Study description

Background summary

Overactive bladder (OAB) syndrome is the most common cause of urinary incontinence and is characterised by the following: urgency (an immediate, unstoppable urge to urinate), with or without urge urinary incontinence (the complaint of involuntary leakage accompanied by or immediately preceded by urgency) usually with frequency (urinating too often and at too frequent intervals) and nocturia (excessive urination at night).
The standard treatment for OAB is currently antimuscarinic drugs, which work by relaxing the muscle within the bladder to help increase the bladder capacity. SVT-40776 belongs to this class of drugs.

Study objective

To evaluate the dose-response relationship of SVT-404776 on efficacy.

Study design

A multicentre, parallel-design. placebo and active-treatment controlled, randomised, double-blind, dose ranging study.

Intervention

Patients will be randomised to receive either 0.05 mg SVT-40776, 0.1 mg SVT-40776, 0.2 mg SVT-40776, 4 mg tolterodine or placebo.

Study burden and risks

Patients will visit the clinic for a total of 5 times every 2 weeks, the duration of a visit will not exceed 3 hours. Patients need to fill out a diary and at every visit they will need to fill out a questionnaire. During every visit a physical examination will take place and an ECG is made and every 4 weeks blood and urine will be collected. Women with childbearing potential need to use an acceptable method of anticonception, and every visit a pregnancy test will be performed. During screening an uroflow, an urological/gynaecological and ophthalmological exam and if necessary a cystometry will be performed.

There may be some side effects and discomforts associated with the study drug. SVT-40776 belongs to the antimuscarinic class of drug. SVT-40776 is in the early stage of development and the extent of the side effects for this drug are not fully known. Early clinical studies suggest that SVT-40776 is well tolerated with dry mouth, visual disturbance and dizziness being the most commonly reported side effects. There may also be side effects and discomforts that are not yet known.

In addition, patients might experience some discomfort from blood sampling and ECG recording. Cystometry usually causes some discomfort and adverse effects. The mild irritation of the urinary tract necessary for insertion of a bladder catheter may occasionally cause flushing, sweating and nausea. Urinary frequency or urgency, and some reddening of the urine, may last for a day after the procedure. There is a slight risk of problems caused by insertion of the catheter and this can lead to infection.

The expected side effects of SVT-40776 are most likely less serious as in other antimuscarinic drugs, and therefore it is useful and justified to investigate the dose-response on effectiveness.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients suffering from OAB based on three cardinal symptoms (urgency with or without urge incontinence, usually accompanied by frequency or nocturia) for at least 6 months prior to inclusion
Patients must document during the 14-day placebo run-in period an average of >< = 10 micturitions/ 24 hours and either a total of >< = 3 incontinence episodes or a total of >< = 3 urgency episodes in the patient diary

Exclusion criteria

Patients with clinically significant bladder neck obstructions defined as post-void residual urine volumes grater than 100mL.

Patients with free uroflow <15 mL/ sec in males or <10 mL/sec in females.
Patients with clinically predominant stress incontinence (>=2 episodes per week)
Patients suffering from neurologic diseases that could cause neurogenic incontinence.
Patients with significant urogenital or gastrointestinal disease.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2006
Enrollment:	13
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Detrol
Generic name:	Tolterodine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	12-06-2006

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2006
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2006
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-04-2007
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-001378-26-NL
CCMO	NL12449.018.06