

Urinary bladder function in patients with overactive bladder syndrome and study of trospium chloride treatment effectiveness depending on urinary bladder changes. The effect of trospium chloride on the cognitive function of patients.

Submission date 08/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/02/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/02/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to evaluate whether urodynamic findings, specifically the presence of detrusor overactivity (DO), predict the efficacy of trospium chloride in treating overactive bladder (OAB) symptoms.

Who can participate?

Patients with no obvious neurogenic disease seeking medical help and complaining of OAB symptoms for at least 6 months

What does the study involve?

All patients underwent routine physical investigation and urodynamic testing, including cystometry and pressure/flow studies. Urodynamic testing was performed to classify patients into two groups: DO (with detrusor overactivity) and WDO (without detrusor overactivity). Patients were treated with either trospium chloride (20 mg twice daily) or placebo for 6 weeks. Primary outcomes include changes in voiding parameters, urgency, nocturia, incontinence episodes, and quality of life as assessed by bladder diaries and questionnaires. During the final week of treatment, patients completed the same questionnaires and a three-day bladder diary.

What are the possible benefits and risks of participating?

Possible benefits: examination and treatment control according to recent guidelines at exact timepoints.

Possible risks: possible adverse events due to trospium chloride treatment.

Where is the study run from?
Municipal City Clinic of Lviv, Ukraine

When is the study starting and how long is it expected to run for?
June 2009 to July 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Taras Ptashnyk, t.ptashnyk@bbtgruppe.de

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Urodynamic findings in patients with overactive bladder syndrome. Is there a difference in treatment effectiveness depending on urodynamic outcomes? The effect of trospium chloride on the cognitive function of patients.

Study objectives

Urodynamic findings in idiopathic OAB patients vary, with some exhibiting detrusor overactivity (DO) while others show stable bladder-filling phases. However, the relationship between urodynamic findings and therapeutic responses to antimuscarinic agents, such as trospium chloride, remains poorly understood. This study aims to evaluate whether urodynamic findings, specifically the presence of detrusor overactivity (DO), predict the efficacy of Trospium Chloride in treating OAB symptoms.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 28/12/2009, Ethics Committee of Municipal City Clinic No. 5 (26 Konovaltsia str., Lviv, 79013, Ukraine; +380322378732; 5kmkl_uoz_lviv@ukr.net), ref: 1189

Study design

Prospective randomized double-blind placebo-controlled study in parallel groups

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Female patients complaining of symptoms of overactive bladder syndrome

Interventions

- An independent pharmacist prepared and randomly assigned the medication or placebo, documenting each kit sequentially starting from number 1. At randomization, patients were assigned to one of the two groups by matching their screening number to the corresponding medication pack. The kit number was unblinded to the investigator at the study's end.
- Patients with symptoms of overactive bladder syndrome, after filling out a bladder diary and questionnaires assessing bladder status and quality of life (ICIQ-UI-SF, IC-OAB, IC-OABqol), will be examined using a urodynamic testing device. Based on the test results, patients will be allocated to groups with or without detrusor overactivity.
- On the same day, patients will be randomized to receive either the recommended dose of trospium chloride (20 mg twice daily) or a placebo for 6 weeks.
- During the last week of treatment, patients will again complete the bladder diary and the aforementioned questionnaires.
- The questionnaires and diaries will be processed by the researcher.

- Parallel to the start and after the treatment, the cognitive function of the patients will be assessed using the Clock Drawing Test and the Trail Making Test.
- Final evaluation of the study results.

Intervention Type

Drug

Pharmaceutical study type(s)

Not Applicable

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Trospium chloride

Primary outcome measure

Trospium chloride effect is measured using the Overactive Bladder Symptoms Score and Overactive Bladder Symptoms Bother at baseline and 6 weeks

Secondary outcome measures

Cognitive function is measured using the Montreal Cognitive Assessment (MoCA) at baseline and 6 weeks

Overall study start date

06/06/2009

Completion date

12/07/2015

Eligibility

Key inclusion criteria

1. Female patients
2. Aged over 18 years
3. Complaining of symptoms of overactive bladder syndrome (urgent urination—at least once a day, frequency of urination—more than 8 times per day, nocturia—more than once per night) with or without urgency urinary incontinence for at least 6 months
4. Not having received treatment with antimuscarinic medications for at least 2 weeks before the study start
5. No diagnosis of painful bladder syndrome
6. Bladder volume greater than 150 ml
7. Sufficiently informed and provided written consent for the use of research data
8. Adequate understanding of the Ukrainian language and ability to complete questionnaires
9. Not participating in any other clinical trials simultaneously

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

Female

Target number of participants

55

Total final enrolment

55

Key exclusion criteria

1. The use of antimuscarinics or other medications affecting bladder activity within one month prior to entering the study
2. Participation in another OAB study
3. Painful bladder syndrome, known neurological disorders (e.g., paraplegia, multiple sclerosis, Parkinson's disease, history of stroke)
4. Stress urinary incontinence (SUI),
5. Active urinary tract infection, confirmed through urine microscopy
6. Infravesical obstruction, grade II or higher vaginal prolapse, or obstructive voiding patterns

Date of first enrolment

17/01/2010

Date of final enrolment

01/02/2015

Locations

Countries of recruitment

Ukraine

Study participating centre

Municipal City Clinic No. 5

26 Konovaltsia str.

Lviv

Ukraine

79013

Sponsor information

Organisation

Municipal City Clinic of Lviv

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

12/04/2025

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the study is stored in the Archive of Municipal City Clinic No. 5, Lviv, Ukraine, and can be available upon request from the authorities of the abovementioned hospital.

IPD sharing plan summary

Available on request