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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

Registration date
11/02/2025

Overall study status
Completed

Last Edited
11/02/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
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79013

Sponsor information

Organisation
Municipal City Clinic of Lviv

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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