Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effect of oral sodium bicarbonate and tolterodine in women with symptoms of overactive bladder and acidic urine

Protocol summary

Study aim

Comparison of the improvement of hyperactive bladder symptoms in women with acidic urine in both groups receiving sodium bicarbonate and tolterodine

Design

The clinical trial consisted of a control group receiving tolterodine with parallel and double-blind randomized groups using the phase 2 permutation block method on 72 patients.

Settings and conduct

Patients referred to Mahdieh Hospital gynecology clinic included all patients over 18 years of agecomplained of overactive bladder symptoms who had these symptoms for at least 12 weeks and did not receive any treatment. The hospital pharmacy received a prescription for sodium bicarbonate and in the tolterodine control group, the patient received the symptoms again after one month according to the questionnaire.

Participants/Inclusion and exclusion criteria

All patients over 18 years of age referred to the gynecology clinic who complained of overactive bladder symptoms who had these symptoms for at least 12 weeks and received no treatment, frequency more than 8 baronacuria more than 2 times and urinary pH less than 6 and lack of rectocystocyst examination voluntarily and voluntarily entered. If the patient does not want to continue taking. Allergic reaction to the drug. The patient becomes pregnant. Reluctance to continue cooperation in the project. They are excluded from the study.

Intervention groups

The first group will be given 500 mg of sodium bicarbonate twice daily and the second group of tolterodine tablets twice daily for one month and randomly. One month later, the patient will be re-evaluated for clinical signs.

Main outcome variables

Oab-v8 questionnaire score before receiving sodium bicarbonate tablets and tolterodine tablets; urinary pH before receiving sodium bicarbonate tablets and tolterodine tablets; oab_v8 questionnaire score after receiving sodium bicarbonate tablets and tolterodine tablets

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131203015634N3**
Registration date: **2022-02-27, 1400/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-27, 1400/12/08**
Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

Tayebeh Jahed Bozorgan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of oral sodium bicarbonate and tolterodine in women with symptoms of overactive bladder and acidic urine

Public title
Evaluation of the effect of oral sodium bicarbonate on the symptoms of overactive bladder and acidic urine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the gynecology clinic included all patients over 18 years of age who voluntarily and knowingly complained of overactive bladder symptoms who had these symptoms for at least 12 weeks and received no treatment, had a frequency of more than 8 times and more than 2 times nocturia, urinary pH less than 6 and lacked of relaxation. Patients under 18 years of age, urinary pH more than 6, kidney stones, stress incontinence, history of abdominal menopause surgery, heart problems, urinary tract infections, malignancies, pelvic pain, neurogenic bladder , Use of antidepressants, anticholinergics, alphablockers, beta-3 agonists, and history of allergies to anticholinergics, sodium bicarbonate, rectocell, cystocell, and uterine prolapse, frequency Less than 8 and nocturia less than 2 in 24 hours are not included in the study.
Exclusion criteria:
If the patient does not want to continue taking. Allergic reaction to the drug. The patient becomes pregnant. Reluctance to continue cooperation in the project. They are excluded from the study.
Age
From **18 years** old to **80 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the table of random numbers, some people are given sodium bicarbonate tablets and others are given tolterodine tablets, so that according to the random numbers table, people with even numbers of sodium bicarbonate tablets are given and people who were given individual numbers are given tolterodine tablets. The number will be 72 and there are two groups, each of which 36 people will enter.
Blinding (investigator's opinion)
Single blinded
Blinding description
The two groups in the first group receive tolterodine and the second group receive sodium bicarbonate. While the tablets are packed in a white pharmacy, respectively, they will be referred to the case and control group after randomization. Patients are not aware of the type of drug given. The patient receives the first package drug and 36 patients receive the second group drug and the analysis is performed
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Mahdieh Hospital, Fadaiyan-e-Islam Blvd.
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1185817311
Approval date
2022-01-04, 1400/10/14
Ethics committee reference number
IR.SBMU.MSP.REC.1400.655

Health conditions studied

1

Description of health condition studied
over active bladder
ICD-10 code
N32.81
ICD-10 code description
Overactive bladder

Primary outcomes

1

Description
OVER ACTIVE BLADDER SCORE POINT
Timepoint
One month after taking the drug
Method of measurement
questionnaire OAB-V8

2

Description
URINE PH
Timepoint
Before administration of tolterodine and sodium bicarbonate at the beginning of the study and one month after receiving tolterodine and sodium bicarbonate
Method of measurement
urine dipstick

3

Description
Oab-v8 questionnaire score based on score before and after receiving tolterodine and sodium bicarbonate
Timepoint
Before administration of tolterodine and sodium bicarbonate at the beginning of the study and one month after receiving tolterodine and sodium bicarbonate
Method of measurement
Scoring based on the score of the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women with acidic urine and hyperactive bladder symptoms over 18 years of age who are randomly selected and treated with sodium bicarbonate 500 twice a day by 36 patients in the intervention group. Sodium bicarbonate tablets produced by Raha Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Control group: Control group: Women with acidic urine and symptoms of hyperactive bladder over 18 years old who are randomly selected and treated with tolterodine 1 mg twice daily in 36 patients in the control group. Tehran Daroo Pharmaceutical Company has been produced.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University of Medical Sciences, Mahdieh Hospita
Full name of responsible person
TAYEBEH JAHED BOZORGAN
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Tayebeh Jahed Bozorgan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
Assistant Professor

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Specialist

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available