

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 Mahdiah Hospital gynecology clinic included all patients over 18 years of age complained 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, alphas blockers, 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.

City

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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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Latest degree

Specialist

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47 / 5,000 Translation results "Shahid Chamran Highway, Yemen Street, Arabi Street"

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47 / 5,000 Translation results "Shahid Chamran Highway, Yemen Street, Arabi Street"

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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