

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Solifenacin and trospium chloride on neurogenic bladder after stroke: a multicentric three arms placebo-controlled trial

Protocol summary

Study aim

Patients with stroke who have bladder dysfunction caused by neurogenic bladder with detrusor overactivity and urinary incontinence can improve their quality of life and reduce the financial burden of renal failure.

Design

3 arm parallel group randomised trial with blinded outcome assessment placebo, solifenacin and trospium chloride

Settings and conduct

Sampling carried out at 2 centers, including the Stroke Registry Center of Imam Reza Hospital of Tabriz Medical University and Athens Greece Hospital Rehabilitation Center. This study is a three-blind randomized controlled clinical trial that the researcher, data collector and analyzer will not know type of the intervention received by the groups. To hide the intervention type allocation based on random allocation sequences written by the non-researcher, the paper will be written in opaque envelopes and in the same package.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Stroke diagnosis patients older than 18 years old, Normal cognitive function with LUTS. Exclusion criteria: Evidence of brain stem or bilateral lesions, psychopathy, Having history of LUTS surgery, pelvic surgery or trauma, Having previous urologic surgery, More than two strokes (diagnosed at a hospital), Other severe neurological disease including dementia, Severe psychiatric disease, Prostate cancer, Patients who refuse consent, Abnormal liver function, closed anterior chamber glaucoma and history of hypersensitive reaction to anticholinergic drugs.

Intervention groups

Intervention group 1- approved antimuscarinic in the treatment of OAB, solifenacin 10 mg, intervention group 2- antimuscarinic approved in the treatment of OAB trospium chloride 20 mg and 3-placebo control group, one oral tablet daily for one Month in all groups.

Main outcome variables

NBSS score; ICIQ-SF score; I-QOL score;

General information

Reason for update

1- Changing the sampling time: Study started later than we expected in scheduled because we had delay in preparing drugs. 2- Reduction in treatment duration from 3months to one month: Most of patients had low compliance in taking drugs for three months, we reduced treatment duration to 1 month. 3- We omitted 3day urinary diary form because most of patients were old with associated disabilities to fill that form accurately. 4- We also changed content of placebo from vitamin E to uniform tablets and without active ingredient. 5- We also omitted sonographic evaluation as we couldn't have a fulltime radiologist in our clinic.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160606028304N2**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **prospective**

Last update: **2023-08-29, 1402/06/07**

Update count: **2**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Ali Pourmohammad

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3381 4472

Email address

alirmd@outlook.com

Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2021-07-01, 1400/04/10

Expected recruitment end date

2022-12-01, 1401/09/10

Actual recruitment start date

2021-07-01, 1400/04/10

Actual recruitment end date

2022-12-01, 1401/09/10

Trial completion date

2022-12-01, 1401/09/10

Scientific title

Efficacy of Solifenacin and trospium chloride on neurogenic bladder after stroke: a multicentric three arms placebo-controlled trial

Public title

Efficacy of Solifenacin and trospium chloride on neurogenic bladder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Stroke diagnosis patients Normal cognitive function Lower urinary tract symptoms Patients with CVA should be ambulatory, able to communicate, and record a voiding diary age ≥ 18 years

Exclusion criteria:

Evidence of brain stem or bilateral signs on examination Mental disorders according to the patient's own statement Having history of LUTS surgery, pelvic and urologic surgery, or trauma Other severe neurological disease including dementia Severe psychiatric disease Prostate cancer Patients who refuse consent Abnormal liver function severe constipation patients with previous history of hypersensitivity reaction to anticholinergics or closed anterior chamber glaucoma

AgeFrom **18 years** old**Gender**

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **201**Actual sample size reached: **201****Randomization (investigator's opinion)**

Randomized

Randomization description

researchers will be randomized patients in these healthing care units, and using www.randomiser.org to simple randomise and the patients IDs will be saved.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The first group will receive one 10 mg tablet solifenacin daily, the second group will receive a 20 mg trospium chloride, and the third group will receive a placebo tablet that will be the same shape, color, and weight.

Participants, the principal investigator, those evaluating the outcome, the Data Safety and Monitoring Committee, and those drafting the article will be blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran National Committiee for Ethics in Biomedical Research

Street address

Emam Reza Hospital, Opposit side of Central Organization of University, Golgasht st.

City

Tabriz

Province

East Azarbaijan

Postal code

5166813145

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.TBZMED.REC.1399.095

Health conditions studied**1****Description of health condition studied**

stroke

ICD-10 code

I67.9

ICD-10 code description

Cerebrovascular disease, unspecified

2**Description of health condition studied**

neurogenic bladder

ICD-10 code

N31.9

ICD-10 code description

Neuromuscular dysfunction of bladder, unspecified

Primary outcomes

1

Description

NBSS score

Timepoint

begining of study and 4 weeks after intervention

Method of measurement

questionnaire

2

Description

ICIQ-UI score

Timepoint

begining of study and 4 weeks after intervention

Method of measurement

questionnaire

3

Description

I-QOL test score

Timepoint

begining of study and 4 weeks after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1, antimuscarinic drug approved in OAB treatment, Solifenacin: this group of patients will be treated with oral solifenacin 10mg tablet daily for 30 days. In this way, the drugs (30 tablets) will be placed inside sealed envelopes and the drug consumption checklist will be provided to the patients and after each drug consumption, the check list will be marked. drug is produced by Behestan Daru pharmaceutical company under the license of astellas company. its also available in market as Vesicare.

Category

Treatment - Drugs

2

Description

Intervention group 2: antimuscarinic drug approved in OAB treatment, trospium chloride: drug used in this group, is trospium chloride 20mg daily for 30 days. In this way, the drugs (30 tablets) will be placed inside sealed envelopes and the drug consumption checklist will be provided to the patients and after each drug consumption, the check list will be marked. This drug is available in the pharmaceutical market under the brand name Spasmax from Zeller Medical Pharmaceutical

Company.

Category

Treatment - Drugs

3

Description

Intervention group, placebo: in this group placebo -made by Associate Pharmacist in uniform shape without pharmaceutical effect- was given to patients. We gave Placebo just like the treatment group once daily for 30 days. In this way, the placebo tablets (30 pieces) will be placed inside sealed envelopes, and the drug consumption checklist will be provided to the patients and after each drug consumption, they will be marked in the relevant checklist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz University of Medical Sciences

Full name of responsible person

Ali Pormohammad

Street address

Emam Reza hospital, Opposit side of Central Organization of University, Golgasht st

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 2073

Email

imamreza@tbzmed.ac.ir

Web page address

<https://imamreza.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Central Organization of University, Golgasht st.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 2073

Email

parvizshahabi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Pormohammad

Position

Urology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Emam Reza hospital, Opposit side of Central Organization of University, Golgasht st.

City

tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3381 4472

Email

alirmd@outlook.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Pormohammad

Position

Urology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Emam Reza hospital, Opposit side of Central Organization of University, Golgasht st.

City

tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 2073

Email

alirmd@outlook.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Pormohammad

Position

Urology resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Emam Reza hospital, Opposit side of Central Organization of University, Golgasht st.

City

tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 2073

Email

alirmd@outlook.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available