Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 out come assessment placebo, sulfinacine 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 accuratly. 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 symptomes 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 patiensts with previous history of hypersensitivity reaction to anticholinergics or closed anterior chamber glaucoma

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

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

Sample size
Target 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 wwww.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
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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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Latest degree
Medical doctor
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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	Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary	