

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of Tadalafil Effects on Function of Detrusor Muscle in Hypocontractile Bladder of Patients Suffering From Spinal Cord Injury

Protocol summary

Study aim

Investigating the effect of tadalafil on bladder function in patients with hypocontractile neurogenic bladder following spinal cord injury

Design

Clinical trial without control group (before-after study), without parallel groups, without blinding, without randomization, on 12 patients

Settings and conduct

The study was conducted in the urology clinic of Imam Reza Hospital in Mashhad, Iran. The study population is 12 patients. Blinding was not done in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: All male patients between the ages of 18-55 years who have neurogenic hypocontractile bladder as a result of spinal cord trauma; at least 6 months have passed since the spinal cord trauma; having hypocontractile bladder in the urodynamic test. Non-inclusion criteria: lack of informed consent; history of sensitivity to phosphodiesterase 5 inhibitors; history of taking drugs containing nitrate compounds; heart problems; history of priapism

Intervention groups

Patients will be given Tadalafil 5 mg, Procial brand produced by Hashtgerd Pharmaceuticals Company in the amount of 45 pills every other night (this pill from Hashtgerd Procial brand is the only brand available in the market It is a medicine of Iran). There is no control group in this study

Main outcome variables

Bladder contraction index; Volume factor of excreted urine; urinary residue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220623055260N1**

Registration date: **2022-07-08, 1401/04/17**

Registration timing: **prospective**

Last update: **2022-07-08, 1401/04/17**

Update count: **0**

Registration date

2022-07-08, 1401/04/17

Registrant information

Name

Mohammad Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Tadalafil Effects on Function of Detrusor Muscle in Hypo-contractile Bladder of Patients Suffering From Spinal Cord Injury

Public title

The effect of tadalafil on spinal cord injury patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All male patients between the ages of 18-55 years old Suffering from hypocontractile neurogenic bladder as a result of spinal cord trauma At least 6 months passed from spinal cord trauma Having hypocontractile bladder in the Urodynamic testing

Exclusion criteria:

lack of informed consent History of sensitivity to phosphodiesterase 5 inhibitors History of taking drugs containing nitrate compounds Heart problems History of priapism

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Mashhad university of medical science

Street address

East door of Ferdowsi University, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-04-26, 1401/02/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.205

Health conditions studied

1

Description of health condition studied

Flaccid neuropathic bladder

ICD-10 code

N31.2

ICD-10 code description

Flaccid neuropathic bladder, not elsewhere classified

Primary outcomes

1

Description

Bladder contraction index (BCI)

Timepoint

Before of beginning of the intervention and 3 or 6 months after the starting intervention

Method of measurement

urodynamic study

2

Description

volume factor of excreted urine

Timepoint

Before of beginning of the intervention and 3 or 6 months after the starting intervention

Method of measurement

urodynamic study

3

Description

Urinary residue

Timepoint

Before of beginning of the intervention and 3 or 6 months after the starting intervention

Method of measurement

urodynamic study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for 3 months, Tadalafil 5 mg from Hashtgerd Pharmaceutical Company's Prucial brand in the amount of 45 pills is given to them every other night (this pill from Hashtgerd's Prucial brand is the only brand available in the Iranian pharmaceutical market) and six months later, Urodynamics re-evaluations are performed in them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahmoud Tavakkoli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ghorbani

Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Associate Professor

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Person responsible for updating data

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Latest degree

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Fax**Email**

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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