Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of Tadalafil Effects on Function of Detrusor Muscle in Hypo-contractile 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; haveing 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)
Phone
+98 51 3462 6165
Email address
ghorbanimh951@mums.ac.ir

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
Street address
Imam Reza Hospital; Ebn-e Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۳۷۹۱۳۳۱۶
Phone
+98 51 3854 3031
Email
tavakkolim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Vice Chancellor for Research and Technology; 3rd Floor; Qarashi Building; Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
+98 51 3843 0249
Email
GhayourM@mums.ac.ir

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
Street address
No. 251, 22 Bahman' 27, 22 Bahman St, Fariman Town
City
Fariman
Province
Razavi Khorasan
Postal code
9391877186
Phone
+98 51 3462 6165
Fax
Email
GhorbaniMH951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahmoud Tavakkoli
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Urology Department, Emam Reza Hospital, Ahmadabad Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3801 2833
Email
tavakkolim@mums.ac.ir

Person responsible for updating data

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
Street address
No. 251, 22 Bahman' 27, 22 Bahman St, Fariman Town
City
Fariman
Province
Razavi Khorasan
Postal code
9391877186
Phone
+98 51 3462 6165
Fax
Email
GhorbaniMH951@mums.ac.ir

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