Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Efficacy of Tadalafil on improvement of erectile dysfunction caused by Covid 19

Protocol summary

Study aim
The aim of this study was to evaluate the effect of Tadalafil administration in accelerating the recovery process of erectile dysfunction caused by COVID 19 disease.

Design
A clinical trial with a control group, with parallel, double-blind, randomized groups performed on 60 patients.

Settings and conduct
In this study, patients with erectile dysfunction after COVID19 referred to the sexual dysfunction clinic of Shariati Hospital in Tehran are evaluated. Individuals are graded according to the International Index of Erectile Dysfunction and randomly assigned to one of the two intervention or control groups. After 2 months, the erectile status is re-examined through a questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Erectile dysfunction after recovery from COVID19, men aged 30 to 50 years, obtaining informed consent Exclusion criteria: Patients with anatomical problems in the penis, history of penile trauma, history of neurological disorders such as spinal cord injuries, stroke and migraine, history of heart disease, history of taking nitrate drugs, diabetes and hypertension

Intervention groups
The intervention group is treated with Tadalafil 10 mg daily for 2 months. The control group received placebo exactly the same as Tadalafil daily for 2 months.

Main outcome variables
Measuring the severity of erectile dysfunction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170807035551N2**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**
Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Iman Shamohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3232 6645

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shamohammadi@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Tadalafil on improvement of erectile dysfunction caused by Covid 19

Public title
Efficacy of Tadalafil on improvement of erectile dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Erectile dysfunction after recovery from C0VID19 Men between the ages of 30 and 50 Obtaining patient consent

Exclusion criteria:

History of erectile dysfunction before COVID19 History of trauma or anatomical problems in the penis A history of neurological disorders including spinal cord injury, stroke, and migraine History of heart disease History of taking mineral nitrate drugs

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are divided into two groups of intervention and control by simple randomization by a table of random numbers. In order to hide random allocation, the method of sealed envelopes is used, in which the type of treatment for each patient is written as even or odd numbers on a piece of paper and is placed in a sealed envelope. After the visit, an envelope is randomly removed for each patient. Doctors and patients do not know the type of treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study. Physician take an envelope, respectively which is blind to the patient's assigned group. According to the assigned number (odd or even numbers), the relevant drug of its therapeutic line is given to the patient. The researcher records the delivered drug code. Patients are also unaware of their treatment group. After completion of the treatment and collecting the data, the analyzer analyzes the data based on their code (odd or even). Evaluators and analyzer will be unaware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Pour Sina alley, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.929

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes

1

Description

Measuring the severity of erectile dysfunction

Timepoint

before intervention, two months after intervention

Method of measurement

International index of erectile function questionnaire

2

Description

Sexual satisfaction of patient

Timepoint

before intervention, two months after intervention

Method of measurement

International index of erectile function questionnaire

3

Description

Intensity of sexual desire

Timepoint

before intervention, two months after intervention

Method of measurement

International index of erectile function questionnaire

Secondary outcomes

1

Description
Complications of drug administration
Timepoint
During the intervention and two months after the start of the intervention
Method of measurement
Based on questions from the patient

Intervention groups

1

Description
Intervention group: Prescribing Tadalafil 10 mg tablets from Rouzdarou company daily 1 tablet after lunch for 2 months.(A total of 60 capsules, each containing a 10 mg tablet of Tadalafil, are prescribed to the patient)
Category
Treatment - Drugs

2

Description
Control group: Prescribe placebo 1 tablet daily after lunch for 2 months.(A total of 60 capsules similar to the intervention group, each containing 10 mg of placebo, are prescribed to the patient)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Shariati Hospital
Full name of responsible person
Iman Shamohammadi
Street address
North Kargar St, Shariati Hospital, Urology Department
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shariatihosp@tums.ac.ir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Center of Tehran University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Kazem Aghamir
Street address
North Kargar St, Shariati Hospital, Urology Department
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Email
shariatihosp@tums.ac.ir
Web page address
https://shariati.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Center of Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Iman Shamohammadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Iman Shamohammadi
Position
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Latest degree
Specialist
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shariatihosp@tums.ac.ir
Web page address
https://shariati.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
Data will be available for re-analysis and also for use in meta-analysis
From where data/document is obtainable
imanshamohammadi@yahoo.com Iman Shamohammadi 09365738466
What processes are involved for a request to access data/document
Inform the responsible person via email and after coordination with Dr.Kazemeyni, the data will be available.
Comments