

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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)

###### Phone

+98 71 3232 6645

###### Email address

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 COVID19 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713135

##### Phone

+98 21 8490 1000

##### Email

shariatihosp@tums.ac.ir

##### Web page address

https://shariati.tums.ac.ir

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713135

##### Phone

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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

Urology

##### Street address

North Kargar St, Shariati Hospital, Urology Department

##### City

Tehran

##### Province

Tehran

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**Web page address**  
<https://shariati.tums.ac.ir>

## Person responsible for scientific 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**  
Urology  
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North Kargar St, Shariati Hospital, Urology  
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shariatihosp@tums.ac.ir  
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## Person responsible for updating data

### 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**  
Urology  
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**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