Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Evaluation of Synergetic effect of Celexib & Tadalafil on Erectile Function in Pateint with Erectile Dysfunction

Protocol summary

Study aim

Evaluation of the effect of celexib that added to standard treatment of erectile dysfunction

Design

Clinical trial with control group, with parallel group, three-way blind, randomized, phase 3 on 50 patients. For randomization, sealed envelopes containing standard drug and placebo as well as similar envelopes containing standard drug and celexib were used.

Settings and conduct

This study will be performed on patients referring to urology clinics of Ghaem and Imam Reza hospitals who have referred due to erection disorder. This study will be randomized-Clinical-Trial. Eligible patients after obtaining informed consent are randomly divided into two groups: 1- The group that in addition to the standard treatment of 5 mg daily tadalafil, will also receive 200 mg of celexib. The group that will receive only the standard 5 mg daily tadalafil treatment with celexib 200 mg placebo. Blinding will be performed for both groups of patients and the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study include the following: Existence of erection disorder in the patient according to the International Index of Erectile Function Questionnaire. Criteria for non-inclusion in the study include the following: Diabetes and heart failure and kidney failure (GFR disorder), patients with mental disorders, concomitant rheumatic diseases, concomitant use of other NSAIDs

Intervention groups

Patients with erectile dysfunction according to the International Erection Index Questionnaire.

Main outcome variables

Increasing the effectiveness of treatment with the addition of celexib in patients with erectile dysfunction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033489N7**
Registration date: **2021-03-16, 1399/12/26**
Registration timing: **retrospective**

Last update: **2021-03-16, 1399/12/26**
Update count: **0**

Registration date

2021-03-16, 1399/12/26

Registrant information

Name

Salman Soltani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2553

Email address

soltanis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of Synergetic effect of Celexib & Tadalafil on Erectile Function in Pateint with Erectile Dysfunction

Public title
Evaluation of Synergetic effect of Celexib & Tadalafil on Erectile Function in Pateint with Erectile Dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Existence of erection disorder
Exclusion criteria:
Diabetes Heart Failure Kidney failure (GFR disorder) History of mental disorder Simultaneous rheumatic disease Taking other NSAIDs

Age
No age limit

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization using sealed envelopes containing standard drug and placebo in one series of envelopes and standard drug and celecoxib in another series of envelopes whose sequence was done randomly with the contents of the envelope from the participant and the researcher and Hidden from clinical caregiver.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants are explained that in addition to standard treatment, the accidental patient may receive additional treatment and will not know whether they will receive additional standard treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Science
Street address
Imam Reza Hospital Research Center, Mashhad, Imam Reza Square , Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191

Approval date
2019-10-12, 1398/07/20

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.720

Health conditions studied

1

Description of health condition studied
Male erectile dysfunction

ICD-10 code
N52.9

ICD-10 code description
Male erectile dysfunction, unspecified

Primary outcomes

1

Description
Percentage Of Patient Discharged From The Erectile Dysfunction

Timepoint
60 Days

Method of measurement
Elimination of erection disorder based on the International Index of Erectile Function Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In addition to standard treatment (5 mg daily tadalafil), the group also consumes 200 mg celexib daily for up to 8 weeks.

Category
Treatment - Drugs

2

Description
Control group: One group received only standard treatment (5 mg tadalafil daily) for 8 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospitah
Full name of responsible person
Salman Soltani
Street address
Bahar Ave, Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3871 3638
Fax
+98 51 3871 3638
Email
webda@mums.ac.ir
Web page address
https://webda.mums.ac.ir/index.php/archive/21-daily-news/health95/medical/24594-2019-10-01-05-14-37

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amirabas Asadpour
Street address
Daneshgah
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3871 3638
Fax
+98 51 3871 3638
Email
webda@mums.ac.ir
Web page address
https://webda.mums.ac.ir/index.php/archive/21-daily-news/health95/medical/24594-2019-10-01-05-14-37

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
Salman Soltani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Daneshgah Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3802 2553
Fax
+98 51 3802 2553
Email
soltanis@mums.ac.ir
Web page address
https://webda.mums.ac.ir/index.php/archive/21-daily-news/health95/medical/24594-2019-10-01-05-14-37

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Salman Soltani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Daneshgah Avenue
City
Mashhad
Province
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Salman Soltani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Urology

Street address
Daneshgah Avenue

City
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is 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
Access starts 6 months after the results are published

To whom data/document is available
Access to data will be unlimited.

Under which criteria data/document could be used
The data request will be unlimited.

From where data/document is obtainable
Dr. Salman Soltani. Urology Department of Imam Reza Hospital, Mashhad, Iran. Phone number 0098 51 3802 2553

What processes are involved for a request to access data/document
After submitting the application, the information will be provided to the applicant as soon as possible.

Comments