

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the Effectiveness of Dapoxetine, Paroxetine, Combination therapy of Dapoxetine/Tadalafil and Combination therapy of Paraoxytine/Tadalafil in treatment of patients with premature ejaculation

Protocol summary

Study aim

Comparison of the Effectiveness of Dapoxetine, Paroxetine, Combination therapy of Dapoxetine/Tadalafil and Combination therapy of Paraoxytine/Tadalafil in treatment of patients with premature ejaculation

Design

controlled clinical trial, Factorial Groups, Not Blinded, Randomized

Settings and conduct

In This Study, Patients will be randomly assigned to study groups using color cards in four colors for each drug group. The study will Consist of 4 Groups and each Group Will Consist of 30 patients. This Study Will Take Place in Emam Reza Hospital Ardabil Branch.

Participants/Inclusion and exclusion criteria

Married men aged between 20 to 50 years old with at least one intercourse in week, less than 2 minutes IELT, without underlying disease, erectile dysfunction and not treated with any psychiatric medication

Intervention groups

First Group Paroxetine 20 mg Tablets (Tehran Shimi Company) Orally, One Tablet Daily for One Month Second Group Dapoxetine 30 mg Tablet (Shafa Pharmaceutical Company) orally, One Tablet One hour before Sex for One Month Third Group Paroxetine 20 mg Tablets (Tehran Shimi Company) Orally, One Tablet Daily for One Month along with Tadalafil 10 mg Tablets (Roozdaru Pharmaceutical Company) Orally One Hour Before Sex For One Month Fourth Group Dapoxetine 30 mg Tablet (Shafa Pharmaceutical Company) orally, One Tablet One hour before Sex for One Month along with Tadalafil 10 mg Tablets (Roozdaru Pharmaceutical Company) Orally One Hour Before Sex For One Month

Main outcome variables

cured Premature Ejaculation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043747N1**

Registration date: **2019-11-08, 1398/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-08, 1398/08/17**

Update count: **0**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Nima Soluki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3352 1698

Email address

nima.soluki@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-29, 1398/06/07

Expected recruitment end date

2019-11-28, 1398/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Dapoxetine, Paroxetine, Combination therapy of Dapoxetine/Tadalafil and Combination therapy of Paraoxytine/Tadalafil in treatment of patients with premature ejaculation

Public title

Effect of Dapoxetine, Paroxetine, Combination therapy of Dapoxetine/Tadalafil and Combination therapy of Paraoxytine/Tadalafil in premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married men aged between 20 to 50 years IELT less than 2 minutes Having at least 1 sexual intercourse in a week

Exclusion criteria:

Having underlying disease including diabetes, hypertension, heart disease, thyroid disease, sexually transmitted disease, and psychiatric disease Treated with any psychiatric medication Erectile dysfunction

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In This Study, Patients will be randomly assigned to study groups using color cards in four colors for each drug group. The study will Consist of 4 Groups and each Group Will Consist of 30 patients.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Deputy of Research and Technology, North side of Ardebil University of Medical Sciences, Daneshgah

Square

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹۸۵۹۹۱

Approval date

2019-08-29, 1398/06/07

Ethics committee reference number

IR.ARUMS.REC.1398.315

Health conditions studied

1

Description of health condition studied

Premature Ejaculation

ICD-10 code

F52.4

ICD-10 code description

Premature ejaculation

Primary outcomes

1

Description

cured Premature Ejaculation

Timepoint

Evaluation of Premature Ejaculation, Two and Four Weeks after Treatment

Method of measurement

Improved or not Improved Intravaginal Ejaculation Latency Time (Two Minutes) measured by the individual

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Paroxetine 20 mg Tablets (Tehran Shimi Company) Orally, One Tablet Daily for One Month

Category

Treatment - Drugs

2

Description

Intervention group: Dapoxetine 30 mg Tablet (Shafa Pharmaceutical Company) orally, One Tablet One hour before Sex for One Month

Category

Treatment - Drugs

3

Description

Intervention group: Paroxetine 20 mg Tablets (Tehran Shimi Company) Orally, One Tablet Daily for One Month along with Tadalafil 10 mg Tablets (Roozdaru Pharmaceutical Company) Orally One Hour Before Sex For One Month

Category

Treatment - Drugs

4

Description

Intervention group: Dapoxetine 30 mg Tablet (Shafa Pharmaceutical Company) orally, One Tablet One hour before Sex for One Month along with Tadalafil 10 mg Tablets (Roozdaru Pharmaceutical Company) Orally One Hour Before Sex For One Month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Bahram Hafezifar

Street address

Next to Islamic Azad University, Basij Square

City

Ardabil

Province

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Postal code

5615731567

Phone

+98 45 3373 3081

Email

e-reza@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahab Bohlooli

Street address

Ardabil Univercity of Medical Science, Daneshgah Blvd

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8599156189

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s.bohlooli@pharmacy.arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Ali Hosseinkhani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Hosseinkhani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences
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Position
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Latest degree
A Level or less
Other areas of specialty/work
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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

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