

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Herbal Tablet containing Ginkgo biloba,- Hypericum perforatum - Epimedium pinnatum - Citrus aurantifolia and Panax ginseng extracts versus Clomipramine and Placebo in the Treatment of Premature Ejaculation

Protocol summary

Study aim

Comparison of the Effectiveness of Herbal Tablet containing Ginkgo biloba,- Hypericum perforatum - Epimedium pinnatum - Citrus aurantifolia and Panax ginseng extracts versus Clomipramine and Placebo in the Treatment of Premature Ejaculation

Design

The total sample size is 150 individuals that are randomly divided into three groups of 50 herbal group, placebo and Clomipramine. The study is done in a three-blinded manner. Patients in the herbal group, two in the Clomipramine group, one in 25 mg tablets, and in the placebo group, consumed one 100 mg starch tablet one to two hours before each intercourse for 2 months and ejaculated before and after After treatment

Settings and conduct

Mostafaviyan Specialized clinic

Participants/Inclusion and exclusion criteria

Inclusion ceriteria: Married men aged 18 to 55 years, Ejaculation duration less than 100 seconds, Men who have been married for at least six months, Getting a score above 8 on the PEDT (Premature Ejaculation diagnostic tool) questionnaire. Inclusion ceriteria: Use of other medicines for premature ejaculation, Alcohol Consumers. Opiods Consumers, Premature ejaculation due to organ failure, Antidepressant drug's Consumers, History of mental's illness, Having severe illnesses (Diabetes Mellitus, Kidney disease and Heart disease)

Intervention groups

The study included three groups of herbal tablet's, Placebo and Clomipramine. One to two hours before intercourse, patients in the herbal group take 2 tablets containing the herbal extracts, patients in the Clomipramine group, One 25mg tablet, and the patients in the placebo group take one 100 mg tablet of starch.

Main outcome variables

Ejaculation time after each intercourse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130911014630N7**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

Registration date

2019-09-01, 1398/06/10

Registrant information

Name

Mohammad Azadbakht

Name of organization / entity

Mazandaran University of Medical Scinecece

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3728

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mazadbakht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-21, 1398/05/30

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Herbal Tablet containing Ginkgo biloba,- Hypericum perforatum - Epimedium pinnatum - Citrus aurantifolia and Panax ginseng extracts versus Clomipramine and Placebo in the Treatment of Premature Ejaculation

Public title
Comparison of the Effectiveness of Herbal Tablet containing Ginkgo biloba,- Hypericum perforatum - Epimedium pinnatum - Citrus aurantifolia and Panax ginseng extracts versus Clomipramine and Placebo in the Treatment of Premature Ejaculation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Married men aged 18 to 55 years Ejaculation duration less than 100 seconds Men who have been married for at least six months Getting a score above 8 on the PEDT (Premature Ejaculation diagnostic tool) questionnaire Premature ejaculation due to organ failure
Exclusion criteria:
Use of other medicines for premature ejaculation Alcohol Consumers Opioids Consumers Antidepressant drug's Consumers History of mental's illness Having severe illnesses (Diabetes Mellitus, Kidney disease and Heart disease)

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, individual, using random numbers table

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, urologists, patients and researchers have no information about herbal tablet or placebo or Clomipramine , and the product has predetermined codes and is randomly given to patients.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Farah abad street

City

Sari

Province

Mazandaran

Postal code

4847191971

Approval date

2019-08-06, 1398/05/15

Ethics committee reference number

IR.MAZUMS.RIB.REC.1398.035

Health conditions studied

1

Description of health condition studied

انزال زودرس

ICD-10 code

F52.4

ICD-10 code description

Premature ejaculation

Primary outcomes

1

Description

Ejaculation Time

Timepoint

After every intercourse

Method of measurement

By the timer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: 325 mg herbal tablets, containing 200 mg Epimedium pinnatum , 50 mg Ginkgo biloba, 40 mg Hypericum perforatum, 20 mg Panax ginseng and 15

mg Citrus aurantifolia. Men take 2 herbal tablet, one to two hours before each intercourse for 2 months and report the time of ejaculation before and after treatment.

Category

Treatment - Drugs

2**Description**

Intervention group II: : Clomipramine group in which patients take a 25 mg tablet one to two hours before each intercourse for 2 months and report ejaculation time before and after treatment.

Category

Treatment - Drugs

3**Description**

Intervention group III: Placebo group in which patients take a 100 mg tablet, containing starch one to two hours before each intercourse for 2 months and report ejaculation time before and after treatment.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Moustafavian Specialty Clinic

Full name of responsible person

Ayoub Barzegarnejad

Street address

Amir Mazandarani Street, Moustafavian Specialty Clinic

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omid.7803@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Faculty of Pharmacy

Full name of responsible person

Dr Mohammad Azadbakht

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Azadbakhtm@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Faculty of Pharmacy

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**

Mazandaran University of Medical Sciences

Full name of responsible person

Omid Sojoudi

Position

Pharmacy Student of Sari University of Medical Sciences

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Mohammad Azadbakht

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

En Results from clinical trials

When the data will become available and for how long

2 Month after print results

To whom data/document is available

Use of results is allowed only with the mention of the source

Under which criteria data/document could be used

for researchers working in Mazandaran University of Medical Sciences

From where data/document is obtainable

Omid sojoudi 00 98 9382878294

What processes are involved for a request to access data/document

Request from the researcher

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Omid Sojoudi

Position

Pharmacy student of Sari University of Medical Sciences

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

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