Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Herbal Tablet containing Ginkgo biloba,- Hypericum perforatum - Epimedium pinnatum - Citrus aurantifulia 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 aurantifulia 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 Scinecee

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3728

Email address

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 aurantifulia 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 aurantifulia 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 Opiods 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 aurantifulia. 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

City
Sari

Province
Mazandaran

Postal code
4847191971

Phone
+98 11 3354 2472

Email
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

Street address
Farah abad street

City
Sari

Province
Mazandaran

Postal code
4847191971

Phone
+98 11 3354 2472

Email
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

Street address
Farah Abad Street

City
Sari

Province
Mazandaran

Postal code
4818974356

Phone
+98 11 3354 2472

Email
Omid.6120@yahoo.com

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
Street address
Farah Abad Street
City
Sari
Province
Mazandaran
Postal code
4847191971
Phone
+98 11 3354 2472
Email
Azadbakhtm@hotmail.com

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
Farah Abad Street
City
Sari
Province
Mazandaran
Postal code
4818974356
Phone
+98 11 3328 2126
Email
Omid.6120@yahoo.com

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