

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessment of effect of clove jell in the treatment for premature ejaculation

Protocol summary

Summary

In this study, the effects of clove jell in the treatment for premature ejaculation are compared to placebo. This study is a double-blind, placebo-control, phase II randomized clinical trial with a sample size of 50 patients. All of the subjects with intravaginal ejaculation latency time less than 1 minutes would be enrolled in the study after considering the general state of health and rule out of erectile dysfunction. After random allocation, subjects divided into two groups and each group received clove jell 1% or placebo. Participants take the drugs for 2 months. All of them record IELT (Intravaginal ejaculation latency time) with a stopwatch four weeks before the intervention and during it. Mean of IELT in the three last intercourse before and during intervention will be compared. The PEDT (premature ejaculation diagnostic tool) questionnaire will be completed for each participant at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013126298N1**

Registration date: **2016-02-13, 1394/11/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-13, 1394/11/24

Registrant information

Name

Ahmad Reza Sharifi Olounabadi

Name of organization / entity

Baqiatallah University of Medical Science,
Department of Traditional Iranian Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 0060

Email address

a-sharifi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahed University of Medical Sciences

Expected recruitment start date

2016-02-14, 1394/11/25

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of clove jell in the treatment for premature ejaculation

Public title

effect of clove in premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: monogamous and heterosexual 18-40 years old man; Intravaginal ejaculation latency time less than 1 minutes; PEDT (Premature ejaculation diagnostic tool) questionnaire score more than eight Exclusion criteria: History of severe or debilitating disease; diabetes; cardiac disease; liver disease; mental disease; thyroid dysfunction; addiction to any drugs or substances; pregnancy of wife; history of hypersensitivity to clove

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

random allocation: table of random digits

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University of Medical Science

Street address

In front of the Holy Shrine of Imam Khomeini, khalij-e-Fars (Tehran-Qom) Highway

City

Tehran

Postal code

3319118651

Approval date

2016-01-25, 1394/11/05

Ethics committee reference number

shahed.REC.1394.55

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

ejaculation latency time

Timepoint

4 weeks before intervention and 2 months during it, 10 minutes before intercourse

Method of measurement

stopwatch

Secondary outcomes

1

Description

Premature ejaculation diagnostic tool questionnaire score

Timepoint

Before and after study

Method of measurement

Questionnaire

Intervention groups

1

Description

clove oil 1%, 10 minutes before intercourse, for 2 months prepared in Shahid Beheshti University of Medical Science, School of Pharmacy

Category

Treatment - Drugs

2

Description

placebo jell

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Family Health Clinic of Shahed University

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Street address

Italy Ave., Palestine Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University of Medical Sciences

Full name of responsible person

Dr. Mohsen Naseri

Street addressTraditional Medicine Clinical Trial Research Center;
No.1471; Between Forsat and Nosrat Ave; North
Kargar Ave; Enghelab Sq.**City**

Tehran

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

Yes

Title of funding sourceVice chancellor for research, Shahed University of
Medical Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shahed University of Medical Sciences

Full name of responsible person

Dr. Ahmad Reza Sharifi Olounabadi

Position

Resident PhD of Iranian Traditional Medicine

Other areas of specialty/work**Street address**Center of TIM Health Care: Third Dashtestan Ave:
Shariati Ave.**City**

Tehran

Postal code**Phone**

+98 21 2288 2596

Fax**Email**

a-sharifi@shahed.ac.ir sharifiahmaddr@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Shahed University of Medical Sciences, Mostfa
Khomeini Hospital**Full name of responsible person**

Dr. Fereidun Khayyamfar

Position

Urologist

Other areas of specialty/work**Street address**

Italy Aven., Palestine Sq.

City

Tehran

Postal code**Phone**

+98 21 8898 5918

Fax**Email**

KHAYYAMFAR@YAHOO.COM

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Dr. Ahmad Reza Sharifi Olounabadi

Position

Resident of Ph.D Iranian Traditional Medicine

Other areas of specialty/work**Street address**

Third Dashtestan Ave: Shariati Ave: Tehran.

City

Tehran

Postal code**Phone**

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*