

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Sep 2026

The effect of caffeine in comparison to conventional squeeze technique on controlling men with premature ejaculation, a Randomized Controlled Trial

Protocol summary

Summary

This is a Randomized Clinical Trial on Iranian Male subjects living in Tehran referred to Tehran psychological and Family clinics. 78 patients were selected randomly into three groups (Random assignment). All groups were assessed for intravaginal Latency Ejaculation Time (ILET) before the intervention. In the first group 50mg caffeine was administered on demand on every sexual contact with a single partner (married men with their wives) 2 hours before intercourse for 2 weeks and their ILET was assessed after this period. the second group were trained for conventional squeeze technique and the same assessment was done. The third group received Placebo. ILET was calculated with chronometer and SSQ and GHQ-28 were also assessed at the end of the study.

General information

Acronym

PEC

IRCT registration information

IRCT registration number: **IRCT2013091614677N1**

Registration date: **2013-10-24, 1392/08/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-24, 1392/08/02

Registrant information

Name

Seyed Hassan Saadat

Name of organization / entity

Baqiatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3250

Email address

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Recruitment status

Recruitment complete

Funding source

Baqiatallah Medical Sciences University

Expected recruitment start date

2013-10-10, 1392/07/18

Expected recruitment end date

2014-04-01, 1393/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of caffeine in comparison to conventional squeeze technique on controlling men with premature ejaculation, a Randomized Controlled Trial

Public title

Effect of on premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION CRITERIA: All marries men (at least 6 months) patients with active sexual intercourse with diagnosed premature ejaculation based on (ICD-10) and functional premature ejaculation (IELT less than 60 seconds) associated with low desire and sexual partner complaint. Patients with other known organic or psychological disorder or patients with drugs or alcohol abuse were not included. **EXCLUSION CRITERIA:** 1-Any other new sexual dysfunction 2- Any other new clinical diagnosis 3- Any

other new psychological disorder 4- Use of any drugs rather than Caffeine for PE during the study 5- Use of any antidepressant and psychotropic drug during the study 6- hyper sensitivity to caffeine in any phase of the study

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Baqiatallah Medical Sciences University

Street address

Mollasadra ave. Vanak Sq.

City

Tehran

Postal code

-

Approval date

2013-01-21, 1391/11/02

Ethics committee reference number

33/2 389 ethic code

Health conditions studied

1

Description of health condition studied

Premature Ejaculation

ICD-10 code

F52.4

ICD-10 code description

The inability to control ejaculation sufficiently for both partners to enjoy sexual interaction.

Primary outcomes

1

Description

Intravaginal Ejaculation Latency Time

Timepoint

every ejaculation for 2 weeks

Method of measurement

Chronometer by Sex Partner

Secondary outcomes

empty

Intervention groups

1

Description

Group 3: intervention with placebo in this group identical tablets to Caffeine (without any effective content) are used.

Category

Placebo

2

Description

Group 1: 50mg caffeine was administered on demand on every sexual contact with a single partner (married men with their wives) 2 hours before intercourse for 2 weeks and their ILET was assessed after this period.

Category

Treatment - Drugs

3

Description

Group 2: using conventional squeezing technique. which is taught to each patient individually and the ILET is measured after 2 weeks of practice.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Psychology and Family clinics

Full name of responsible person

Seyed Hassan Saadat

Street address

Baqiatallah Medical Sciences University: South Sheikh Bahaee St., Mollasadra Ave., Vanak Sq.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behavioral Sciences resaerch Cener

Full name of responsible person

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Tehran

Grant name**Grant code / Reference number**

389

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

Yes

Title of funding source

Behavioral Sciences resaerch Cener

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Vice chancellor for research (BMSU)

Full name of responsible person

Dr. Morteza Izadi

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Mollaasadra Ave. Vanak Sq.

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Tehran

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 (BMSU)

Proportion provided by this source**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

Baqiatallah Medical Sciences University

Full name of responsible person

Seyed Hassan Saadat

Position

Psychologist , MD; Deputy of Research Department

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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