

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of local traditional medicine product based on Nigella Sativa on premature ejaculation -A ranomized triple blind placebo controlled traial

Protocol summary

Summary

Objective: This study examined the qualitative and quantitative impact of this natural product on patients with premature ejaculation and it provided production requirements. Study design: randomized, triple-blind, placebo-controlled, stage three clinical trials study. Population: the men married more than six months and they are not satisfied from the time of ejaculation. Sample size: 76. Interventions: prescription of drug and placebo locally on penis and scrotum and perineum area.. Intervention time: every night before going to bed half-hour before intercourse. Primary outcome study of quantitative and qualitative improvement of premature ejaculation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122931645N1**

Registration date: **2017-01-13, 1395/10/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-13, 1395/10/24

Registrant information

Name

Seyedhamed Moosaviasil

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3376 5379

Email address

h-moosaviasil@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

traditional medicine faculty of Tehran university of medical scince

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local traditional medicine product based on Nigella Sativa on premature ejaculation -A ranomized triple blind placebo controlled traial

Public title

EFFECT OF "KANDO OIL" ON PREMATURE EJACULATION

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. The men 20 to 40 years old. 2. Steady sexual activity at least 6 month with a female partner. 3. The history of premature ejaculation more than 6 months. 4. Time IELT less than 1 minute. 5. The ability to begin and maintain an erection (IIEF score of 22). 6. Sexual intercourse at least one time per week. 7. Informed consent of patient to entering the project and filling the consent form from him. None Inclusion criteria: 1. A history of severe organic diseases such as uncontrolled diabetes, heart failure, acute renal failure, urinary surgery, urinary tract infections in male and partner. 2. A history of severe psychiatric illness and poor mental state. 3. PEDT questionnaire score less than

11. 4. The history of alternate premature ejaculation. 5. Erectile Dysfunction (IIEF score less than 22) 6. Anatomic abnormalities of the penis that causes unsuccessful penetration. 7. Substance abuse such as alcohol, opium and smoking. 8. Using drugs that affect the sexual function, including phosphodiesterase inhibitors and selective serotonin reuptake inhibitors and opioids and antidepressants and anti-anxieties and hormonal drugs during project. 9. Extreme hot and dry temperament. 10. The warm and wet temperament with semen acuity. 11. Any history of hypersensitivity to black cumin, frankincense and olives. 12. The history of any type of mucosal and dermal allergy. Exclusion criteria: 1. using of drugs and substance that effective on sexual performance. 2. Intercourse activity less than twice in three weeks. 3. The using of condom and local anesthetic. 4. The sever decrease in male libido or sexual partner. 5. The use of any vaginally cream, ointment or gel by partner. 6. Severe and intolerable adverse events associated with the drug based on a questionnaire PRO-CTCAE. 7. The Withdrawing of participant from continuing the project with any reason.

Age

From **75 years** old to **55 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

tehran university of medical scinse

Street address

Tehran, Keshavarz Blvd. and Ghods Crossroads,
Tehran University of Medical Sciences Headquarters
Building, fifth floor, Room 501

City

tehran

Postal code

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1315

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

Time to Ejaculation

Timepoint

before & 3 weeks after intervention

Method of measurement

PEDT qustioner - chornometer

Secondary outcomes

1

Description

sexuall desire

Timepoint

before & 3 weeks after intervention

Method of measurement

IIEF qustioner

Intervention groups

1

Description

The placebo prescribed for once every night and halfhour before sexual intercourse for 3 weeks. For anytime placebo used locally two puffs (each puff about 25/0 cc) on the penis and two puffs scrotum and two puffs perineal area.

Category

Treatment - Drugs

2

Description

The drug prescribed for once every night and halfhour before sexual intercourse for 3 weeks. For anytime drug used locally two puffs (each puff about 25/0 cc) on the penis and two puffs scrotum and two puffs perineal area.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

traditional medicine clinic

Full name of responsible person

syed hamed moosaviasil

Street address

Enghelab st.-college bridge- Khark st.-near the court

City

tehran

2

Recruitment center

Name of recruitment center

urology clinic of sina hospital

Full name of responsible person

Street address

City

tehran

3

Recruitment center

Name of recruitment center

ahmadiyah clinic

Full name of responsible person

Street address

City

tehran

4

Recruitment center

Name of recruitment center

toba clinic

Full name of responsible person

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

trita company

Full name of responsible person

mohammad mahdi ahmadianattary

Street address

alborz university of medical scinse

City

karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

trita company

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

tradiional medicine faculty of TUMS

Full name of responsible person

mysam shirzad

Street address

tradiional medicine faculty of TUMS

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

tradiional medicine faculty of TUMS

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

TUMS

Full name of responsible person

syedhamed moosaviasil

Position

traditional medicine PHD student

Other areas of specialty/work

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Full name of responsible person

syed hamed moosaviasil

Position

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Other areas of specialty/work

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City

Postal code

Phone

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