

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of highsense barij containing Tribulus Terrestris extract, Panax ginseng and L-arginine on male libido and comparing with placebo

Protocol summary

Study aim

1. Determining and comparing marital satisfaction before and after drug use in two groups treated with Highsense and placebo 2. Determining and comparing the level of sexual desire from the marital relationship before and after taking the drug in the group treated with Highsense and placebo 3. Determining and comparing the rate of erectile dysfunction before and after taking the drug in the group treated with Highsense and placebo 4. Determining and comparing the rate of orgasm before and after taking the drug in the group treated with Highsense with placebo Determining and comparing the level of overall satisfaction before and after taking the drug in the group treated with Highsense drug with placebo Determining and comparing the frequency of side effects after taking the drug in the group treated with Highsense with placebo

Design

Clinical trial with control group, with 2 parallel groups, double-blind, randomized, phase 3 participating with 100 patients.

Settings and conduct

Patients are referred to a researcher by a specialist and enter the trial. Location: Boostan specialized clinic in Kermanshah. Researcher-physician-analyzer-statistician and patients are blinded

Participants/Inclusion and exclusion criteria

suffering erection dysfunction

Intervention groups

Highsense Barij contains ginseng extracts of ginseng and L-arginine versus placebo (placebo)

Main outcome variables

1. Erection rate 2. The satisfaction with the relationship rate 3. The sexual desire rate(Libido)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130722014106N8**

Registration date: **2020-12-17, 1399/09/27**

Registration timing: **prospective**

Last update: **2020-12-17, 1399/09/27**

Update count: **0**

Registration date

2020-12-17, 1399/09/27

Registrant information

Name

Reza Tahvilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6482

Email address

rtahvilian@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

2021-02-19, 1399/12/01

Actual recruitment end date

2021-11-22, 1400/09/01

Trial completion date

2022-02-20, 1400/12/01

Scientific title

The effect of highsense barij containing Tribulus Terrestris extract, Panax ginseng and L-arginine on male libido and comparing with placebo

Public title

evaluation of highsense barij effectiveness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

suffering erection dysfunction

Exclusion criteria:

Renal Failure Heart Failure Hypo Tension history Spinal Cord Injury Liver Failure

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method (Permuted block randomization) so that first all 4 blocks which include two codes A and B are prepared (6 blocks) then random tables of random blocks are selected using placement. These blocks form a sample-sized sequence of codes A and B, each of which is randomly assigned to one of the groups. The list of relevant codes will remain in the formulation section of Barij Essence pharmaceutical Company until the completion of the project. This method will provide both blinding and randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both tablets are available in the same package, size, shape and color, and until decoded, the executors will not know the nature of the drugs. Also, for statistical analysis, the statistician is unaware of the type of drug and knows two groups called A and B. All the information of the drug code is in the formulation section of Barij Essential Oil Pharmaceutical Company and after the completion of the project, the real names of the groups will be determined

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Ave

City

Kermanshah

Province

Kermanshah

Postal code

6714869914

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.KUMS.REC.1399.568

Health conditions studied**1****Description of health condition studied**

erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes**1****Description**

Score in the IIEF (international index of erection function) questionnaire

Timepoint

Beginning of treatment and end of treatment (6 weeks)

Method of measurement

international index of erection function questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Drug receiving group :500 mg Highsense Barij tablets made by Barij Essence Pharmaceutical Company containing ginseng, Tribulus terrestris extract and L-arginine standardized containing 100 mg of total Saponin extract in each tablet Administer twice a day, one hour after lunch and dinner with a glass of water for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Control group to receive placebo :500 mg non-drug containing tablets made by Barij Essence Pharmaceutical Company and similar to the treatment group, they will take two tablets a Day an hour after lunch and dinner with a glass of water for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah university of medical sciences , faculty of pharmacy

Full name of responsible person

Reza Tahvilian

Street address

Daneshgah Ave. , Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3427 6480

Email

rtahvilian@kums.ac.ir

Web page address

<https://pharmacy-school.kums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

Street address

Shahid Beheshti Ave

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3835 8943

Email

rkhodarahmi@kums.ac.ir

Web page address

<https://kums.ac.ir>

Grant name

Reza Khodarahmi

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Tahvilian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Danedhgah Ave , Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3427 6489

Email

rtahvilian@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Tahvilian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Daneshgah Ave , Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3427 6480

Email

rtahvilian@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Tahvilian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Daneshgah Ave , Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3427 6480

Email

rtahvilian@kums.ac.ir

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The main consequences are shared after the intervention in the disease

When the data will become available and for how long

One year after publishing the results

To whom data/document is available

Physicians, pharmacists, medicinal professionals and other industrial pharmacy staff.

Under which criteria data/document could be used

Researchers, physicians and medicinal and pharmacy students

From where data/document is obtainable

Contact with executor of the project

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

Requesting by sending email

Comments