Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of highsense barij containinig 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)

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+98 83 1427 6482

Email address

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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 containinig 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 theIIEF(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 scienses , faculty of pharmacy

Full name of responsible person
Reza Tahvilian

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Daneshgah Ave. , Parastar Blvd

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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

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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

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Person responsible for scientific inquiries

Contact

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Kermanshah University of Medical Sciences

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Person responsible for updating data

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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