Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Alpinia officinarum Hance and placebo in men with abnormal semen sperm

Protocol summary

Study aim

This study is a clinical trial to investigate the effect of Alpinia officinarum Hance on spermogram factors.

Design

The target population consists of eligible patients referred to The Fatima Al-zahra Infertility Center of Babol University of Medical Sciences diagnosed with impaired spermatogenesis (Oligospermic, Teratospermic and Asthenospermic) .This study will be conducted in two groups in parallel for three months. The number of participants, 30, was considered enough according to the relevant literature. All the participants will be checked by an urologist so that they meet the criteria for impaired spermatogenesis (Oligospermia, Teratospermic and Asthenospermic); simple consecutive sampling was used and the participants gave their full consent.

Settings and conduct

The scope pf this Double-blind study will be limited to The Fatima Al-zahra Infertility Center. Before administration of drugs, a semen Analysis will be in order and the drugs will be coded as A and B. In the intervention group, 3 grams of Alpinia officinarum Hance powderin was administered in 1-gram capsules per day. The control group will receive placebo capsules (sucrose). At the end, the results of a second semen analysis (post-test) will be compared to the innital ones in terms of seminal volume, sperm count, motility and morphology.

Participants/Inclusion and exclusion criteria

Inclusion criteria : idiopathic oligospermia disorder; idiopathic Teratospermic disorder; idiopathic Asthenospermia disorder. Exclusion criteria:azoospermia; Pretesticular disorder such as endocrine disorders (hyperprolactinemia, congenital adrenal hyperplasia, ...); Chromosomal disorders such as Klinefelter, men XX, XYY; known Testicular dysfunction such as varicocele or orchitis or Cryptorchidism; Post testicular dysfunction such as the mechanical obstruction, impaired embryo transfer or functional obstruction, vasectomy and; A history of treatment for infertility in the past three month; Medication history affecting semen; History of anti-metabolite drugs ;Diabetics patients; Hypo-and hyperthyroidism patients; History of chemotherapy; A history of cerebrovascular diseases ; A history of exposure to radiation or radioactive radiation

Intervention groups

In the intervention group, 3 grams of Alpinia officinarum Hance powder will administer in 1-gram capsules per day For three months. Control group will receive placebo capsules (sucrose).

Main outcome variables

Spermogram factors including sperm volume؛ sperm count؛sperm morphology; sperm motility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103130616N1**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **prospective**

Last update: **2018-01-20, 1396/10/30**
Update count: **1**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Fatemeh Kolangi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date
2017-02-23, 1395/12/05
Expected recruitment end date
2017-06-22, 1396/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Alpinia officinarum Hance and placebo in men with abnormal semen sperm

Public title
Comparison of Alpinia officinarum Hance and placebo on spermogram test
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria : idiopathic oligospermia disorder; idiopathic Teratospermic disorder; idiopathic Asthenospermia disorder
Exclusion criteria:
Exclusion criteria:azoospermia; Pretesticular disorder such as endocrine disorders (hyperprolactinemia, congenital adrenal hyperplasia, ...); Chromosomal disorders such as Klinefelter, men XX, XYY; known Testicular dysfunction such as varicocele or orchitis or Cryptorchidism; Post testicular dysfunction such as the mechanical obstruction, impaired embryo transfer or functional obstruction, vasectomy and; A history of treatment for infertility in the past three month; Medication history affecting semen; History of anti-metabolite drugs ;Diabetics patients; Hypo-and hyperthyroidism patients; History of chemotherapy; A history of cerebrovascular diseases ; A history of exposure to radiation or radioactive radiation
Age
No age limit
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants, principal investigator, health personnel assigned to the study groups are kept blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Babol University of Medical Sciences
Street address
University of Medical Sciences, Ganjafrooz Street
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2016-12-24, 1395/10/04
Ethics committee reference number
MUBABOL.HRI.REC.1395.57

Health conditions studied

1

Description of health condition studied
Sperm disorders
ICD-10 code
N50.9
ICD-10 code description
Disorder of male genital organs, unspecified

Primary outcomes

1

Description
sperm motility
Timepoint
Before the treatment & Three months after taking the drug and placebo
Method of measurement
spermogram

2

Description
Sperm morphology
Timepoint
Before the treatment & Three months after taking the drug and placebo
Method of measurement
spermogram

3

Description
Sperm Count
Timepoint
Before the treatment& Three months after taking the drug and placebo
Method of measurement
spermogram

4

Description
Sperm volume
Timepoint
Before the treatment
Method of measurement
spermogram

Secondary outcomes

1

Description
Volume of semen
Timepoint
Three months after taking the drug and placebo
Method of measurement
spermogram

2

Description
Sperm Count
Timepoint
Three months after taking the drug and placebo
Method of measurement
spermogram

3

Description
sperm motility
Timepoint
Three months after taking the drug and placebo
Method of measurement
spermogram

4

Description
Sperm morphology
Timepoint
Three months after taking the drug and placebo
Method of measurement
spermogram

Intervention groups

1

Description
In the intervention group, 3 grams of Alpinia officinarum Hance powder in will administer in 1-gram capsules per day For three months.
Category
Treatment - Drugs

2

Description
The control group, 3 grams of placebo capsules (sucrose) will receive on a daily for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
The Fatima Al-zahra Research Center for Fertility and Infertility
Full name of responsible person
Fatemeh Kolangi
Street address
University of Medical Sciences, Ganjafrooz Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Doctor Ali Akbar Moghadam Nia
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Vice chancellor for research,University of Medical Sciences, Ganjafrooz Street
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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, Babol 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
Babol University of Medical Sciences
Full name of responsible person
Zahra Memariani
Position
Traditional Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available