

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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 of 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 powder in 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 initial 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)

##### Phone

+98 11 3219 4730

##### Email address

f.kolangi@mubabol.ac.ir

**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 will be administered 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 basis 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

#### **City**

Babol

#### **Province**

Mazandaran

#### **Postal code**

47176-47745

#### **Phone**

+98 11 3219 2832

#### **Email**

f.kolangi@mubabol.ac.ir

## **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

#### **Street address**

Vice chancellor for research, University of Medical Sciences, Ganjafrooz Street

#### **City**

Babol

#### **Province**

Mazandaran

**Postal code**

47176-47745

**Phone**

+98 11 3219 7667

**Email**

moghadamnia@yahoo.com

**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**

**Street address**

University of Medical Sciences, Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-47745

**Phone**

+98 11 3219 4730

**Fax**

**Email**

z.memariani@mubabol.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Seyyedali Mozaffarpour

**Position**

Assistant Professor Faculty

**Latest degree**

Ph.D.

**Other areas of specialty/work**

**Street address**

University of Medical Sciences, Ganjafrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-47745

**Phone**

+98 11 3219 4730

**Fax**

**Email**

seyyedali1357@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Kolangi

**Position**

PHD Student of Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

**Street address**

University of Medical Sciences, Ganjafrooz Street

**City**

babol

**Province**

Mazandaran

**Postal code**

47176-47745

**Phone**

+98 11 3219 4730

**Fax**

+98 11 3219 4728

**Email**

F.kolangi@mubabol.ac.ir

**Web page address**

## 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