

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Herbal composition on sex hormones level: a Single-blinded, comparative controlled clinical trial

Protocol summary

Study aim

Objective of this study: The results proved the effectiveness of the herbal composition on sex hormones as well as prolactin in infertile men.

Design

Clinical trial, single-blind and comparative

Settings and conduct

This study was performed during 2014-2015 in the infertility clinic of Umm Leila in Bandar Abbas. Fifty infertile men aged 22-42 years were randomly selected by inclusion criteria and 30 patients in the intervention group received two 500 mg capsules daily including herbal composition. The 20 patients in the control group received a placebo twice a day, in the morning and evening for three consecutive months. At the end of the three-month period, the ability of sperm and sex hormones and prolactin criteria in the intervention group was evaluated and compared with before taking herbal supplements and the control group. The person collecting information and analyzing the study was completely blind to all the information of the groups and the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infertile men between 22 and 42 years of age, sperm count < 20 million per milliliter, morphology < 20%, progressive motility < 50%
Exclusion criteria: varicocele, testicular atrophy, azoospermia.

Intervention groups

The intervention group, besides a standard infertility medical treatment prescribed by a physician, received two 500mg capsules on a daily basis containing an herbal composition of palm pollen essence (350 mg) and black seed powder (250 mg) in the morning and at night for 3 months. Control group: In addition to receiving standard infertility medication, patients also received two 500 mg placebo capsules in the morning and night for three months.

Main outcome variables

Changes in sperm parameters, sex hormones and prolactin

General information

Reason for update

Edition and revision of the research methodology: As these data describe an invention, The content needs to be updated now. Thus, it received a new ethical code from the ethical committee

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020120895N1**
Registration date: **2015-11-08, 1394/08/17**
Registration timing: **retrospective**

Last update: **2021-09-24, 1400/07/02**

Update count: **1**

Registration date

2015-11-08, 1394/08/17

Registrant information

Name

Soghra Fallahi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 7192

Email address

lfallahi@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical sciences

Expected recruitment start date

2015-01-31, 1393/11/11

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

2015-01-31, 1393/11/11

Actual recruitment end date

2015-06-22, 1394/04/01

Trial completion date

2015-06-22, 1394/04/01

Scientific title

The effect of Herbal composition on sex hormones level: a Single-blinded, comparative controlled clinical trial

Public title

Evaluating the effect of an herbal complement on sex hormones in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile men between 22 and 42 years of age No allergy to the consumption of herbal medicines Sperm count less than 20 million per milliliter morphology < 20% progressive motility < 50%

Exclusion criteria:

history of genetic disorder anomaly in reproductive system Consumption of fertilizing drugs for at least 6 months before participating in this study Varicocele Testicular atrophy Azospermia Ejaculation disorder Candidate for intracytoplasmic injection of sperm unwillingness to take part in the study trauma to testicles alcohol abuse history of systemic disorder

Age

From **22 years** old to **42 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **62**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is provided with a sealed envelope. In this method, a number of cards selected by the researcher as the intervention group and the same number of cards for the control group are considered; Then, by merging the cards together (flipping the cards), a card is taken out and its allocation is recorded, and that card is returned to the other cards after being taken out. The cards are then merged again and another card is removed. This process continues until a random sequence is reached according to the sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collector who evaluates the outcome has no information about the coded packets and their contents

and does not know what kind of intervention the intervention group and the control group will receive.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethis ommittee of Bandar Abbas University of Medical Sciences

Street address

Fertility and infertility research enter, Shahid Mohammadi Hospital, Kamarbandi st., Jomhuri Eslami Blvd., Bandar Abbas, Hormozgan, Iran.

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2016-03-04, 1394/12/14

Ethics committee reference number

IR.HUMS.REC.1394.201

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

Male infertility

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

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

Sperm Motility

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Determination of sperm motility using CASA computer system

2**Description**

Sperm count

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Determination of sperm count using CASA computer system

3

Description

The amount of LH

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Measurement of LH by Radioimmunoassay

4

Description

The amount of FSH

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Measurement of FSH by radioimmunoassay

5

Description

The amount of prolactin

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Measurement of prolactin by Radioimmunoassay

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, besides a standard treatment prescribed by an urologist, received two 500 mg capsules containing 350 mg of pollen essence powder and 250 grams of black seed powder every morning and night for three months. Within 90 days, every patient received 180 capsules in sealed coded envelopes. The herbal composition capsules were manufactured by the Golbadistan Company.

Category

Treatment - Drugs

2

Description

The control group received 180 capsules of placebo(500 mg) in the same shape and color as the medicine used in

the intervention group besides the standard treatment for 3 months. The placebo was manufactured by Golbadistan Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Umm Leila Fertility and Infertility Clinic

Full name of responsible person

Soghra Fallahi

Street address

Umm Leila Hospital, Infertility Clinic, Enghelab St. Bandar Abbas, Iran

City

Bandar-e Abbas

Province

Hormozgan

Postal code

7915868462

Phone

+98 76 3333 7192

Fax

+98 76 3333 7192

Email

fallahi.leila@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Teimour Aghamolaei

Street address

Vice-chancellor for research, East side of the hospital, Shahid Mohammadi Hospital, Jomhuri Eslami Bld, Bandar Abbas, Hormozgan, Iran

City

Bandar-e Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3371 0393

Fax

+98 76 3371 0393

Email

taghamolaei@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr Soghra Fallahi
Position
PhD in Reproductive Biology
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Fertility/Infertility Research Center, Ring road,
Jomhuri Islami Blvd., Shahid Mohammadi Hospital,
Bandar Abbas, Iran.
City
Bander-e Abbas
Province
Hormozgan
Postal code
09173691399
Phone
+98 76 3333 7192
Fax
+98 76 3333 7192
Email
fallahi.leila@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr Soghra Fallahi
Position
Reproductive biology PhD student
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Fertility and Infertility Research Center, Shahid
Mohammadi Hospital, Kamarbandi St, Jomhuri Eslami
Blvd, Bandar Abbas, Hormozgan, Iran

City
Bander-e Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 7192
Fax
+98 76 3333 7192
Email
fallahi.leila@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr Soghra Fallahi
Position
Reproductive biology PhD student
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Fertility/Infertility Research Center, Ring road,
Jomhuri Islami Blvd., Shahid Mohammadi Hospital,
Bandar Abbas, Iran.
City
Bandar-e Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 7192
Fax
+98 76 3333 7192
Email
fallahi.leila@gmail.com
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

No - There is not 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