Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Soghra Fallahi
Name of organization / entity
Hormozgan University of Medical Sciences
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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 researh 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr.Teimour Aghamolaei

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

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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

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

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Latest degree

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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

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