Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Effect of the “Compound honey syrup” on spermatogenesis in infertile men

Protocol summary

Study aim
Effect of the “compound honey syrup” on spermatogenesis in infertile men

Design
Randomized control trial- Double Blind Study. With Control group. Sample size=76 precipitant. Randomization by R software and dual blocks.

Settings and conduct
After determining the sample size and categorization of patients in the control and treatment groups, the general information of the patients including the age and duration of infertility, medical history, as well as the results of the first semen analysis test include count , shape and sperm motility will also be recorded. Then, in treatment group, for 90 days, the compound honey syrup (0.5ml/kg/day) + Tab Vit E 100iu daily will be prescribed . and in control group the same proportion of placebo syrup + Vit E 100iu will be used. This study will be planned in Shariat panahi clinic. Blinding is planned carefully.

Participants/Inclusion and exclusion criteria
inclusion criteria: Infertility or subfertility documented with sperm analysis including sperm count, morphology and/or motility disorders Infertility history more than one year. patients are available Men with age between 20 to 50 years old exclusion criteria: Testicular atrophy or structural diseases or congenital malformations of the genital tract Feverish and infectious diseases Have a history of allergic reactions to drug or placebo compounds Varicocele Taking chemotherapy drugs - anticoagulants - testosterone, anti-androgens Severe systemic diseases

Intervention groups
Intervention groups include infertile men with spermatogenesis disorder(count-morphology and or motility). In both groups, vitamin E tablets are used for 90 days as a common treatment in addition to compound honey syrup (in the intervention group) and placebo with exactly the same appearance (in the control group).

Main outcome variables
sperm count sperm morphology sperm motility

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220102053605N1**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date
2022-06-05, 1401/03/15

Registrant information
Name
Farrokh Eftekhar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8877 3521
Email address
feftekhar@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-28, 1401/03/07
Expected recruitment end date
2022-12-28, 1401/10/07
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of the “Compound honey syrup” on spermatogenesis in infertile men

Public title
Effect of the “Compound honey syrup” on spermatogenesis in infertile men

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infertility or subfertility documented with sperm analysis :1-sperm count between 7 to 12 millions/ml AND OR .2-with any defect in morphology and motility state. Infertility history more than one year. patients are available Men with age between 20 to 50 years old.

Exclusion criteria:
Testis Atrophy or other urogenital structural or congenital diseases Infectious diseases-prostate or testis infectious diseases Allergy to medication or placebo components Varicocele Chemotherapy-anti coagulant therapy-Androgen or anti androgen therapy Sever systemic diseases smoking or addiction

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method are made with Permuted blocks .Equal block size .Two group or block A and B. After entering the study, individuals are placed in one of groups A or B. The medication is coded in exactly the same packages and the delivery assistant is based on the sealed envelope that the medication is given to the participant. And does not know whether it is a medication or a placebo. Sample size of 76 people (38 people in each group)

Blinding (investigator's opinion)
Double blinded

Blinding description
Medication and placebo are made in the company by people who are not involved in the study and will be packaged and coded in the same way. The person doing the coding will not have a role in the study until the end of the intervention. The prescribing physician, assistant, and patient will not be aware of any of the contents of the medications, and the medication code will be written on the patient's paper. (double blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2022-05-16, 1401/02/26

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.064

Health conditions studied

1

Description of health condition studied
Male infertility

ICD-10 code
N46

ICD-10 code description
Male infertility

Primary outcomes

1

Description
sperm count

Timepoint
Before the intervention and after the intervention(intervention period is 90 days)

Method of measurement
Semen Analysis

2

Description
sperm motility

Timepoint
Before the intervention and after the intervention(intervention period is 90 days)

Method of measurement
Semen Analysis

3

Description
sperm morphology
Timepoint
Before the intervention and after the intervention(intervention period is 90 days)
Method of measurement
Semen Analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to Vit E 100IU /day, in the experimental group, compound honey syrup(consisting of honey, ginger, cinnamon, cardamom, saffron and Alpinia officinarum) is also prescribed. Consumption of compound honey syrup, 0.5 ml/kg at 24 h in divided 3 doses(An average of 40 cc per 80 kg person). Each Dose(about 13 cc) Mixes in 100 cc of boiled and lukewarm three time a day 30 minutes after the meal. The study period is 90 days. In the first visit, the participants will be provided with the method of consumption and the daily use table of the medicine. Any ambiguity or question of the participants will be answered via SMS. They will be visited again and the possibilities will be discussed.
Category
Treatment - Drugs

2

Description
Control group: intervention includes consumption of placebo syrup in 200 ml bottles quiet the same as compound honey syrup and consisting of(water, CMC 0.7, Acesulfame potassium 0.05%, sunset yellow 0.003%, tartrazine0.002%, color additives) In addition to VIt E 100IU /day, in the control group, placebo syrup is also prescribed. Consumption of placebo, 0.5 Ml/kg at 24 h in divided 3 doses. Each Dose Mixes in 100 cc of boiled and lukewarm three time a day 30 minutes after the meal(An average of 40 cc per 80 kg person and each dose about 13 cc). The study period is 90 days. Placebo syrup is made by the pharmaceutical group of NIAK company. In the first visit, the participants will be provided with the method of consumption and daily schedule of drug use. Any ambiguity or question of the participants will be answered via SMS. Once in the middle of the course, the participant are visited and ambiguities about problems or possible complications will be discussed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariat Panahi traditional Clinic
Full name of responsible person
DR. Roshanak Mokaberinezhad
Street address
No.8, , shams Ali;Valiasr Ave.
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
Rmokaberi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sponsor Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak,
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9781
Email
Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farrokh Eftekhar

Position
PhD student of traditional Persian medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8877 2521

Email
drfarrokheftekhar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Roshanak Mokaberinejad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St,

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8877 2521

Email
mokaberi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farrokh Eftekhar

Position
PhD student of traditional Persian medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St,

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8877 2521

Email
Drfarrokheftekhar@gmail.com

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
Not applicable

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