

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of sleep hygiene education and diet based on Persian traditional medicine texts on the results of in vitro fertilization (IVF/ICSI) of infertile women

Protocol summary

Study aim

Determining the effect of sleep hygiene education and diet based on Iranian traditional medicine texts on the results of in vitro fertilization (IVF/ICSI) of infertile women.

Design

Randomized controlled clinical trial with 2 control and intervention groups on 124 patients, and the random allocation process will be done with Random Allocation 2.0 software.

Settings and conduct

Imam Khomeini Hospital (RA), Sari City, Infertility Treatment Center, the samples were entered into the study as available and divided into two control and intervention groups by random allocation. In this study, there is a possibility of blinding at the level of outcome evaluation and analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 45 years, the satisfaction of couples (self and spouse) to participate in the study, primary or secondary infertile women (with a history of previous pregnancy) with ovarian problems or infertility with unexplained causes, exclusion criteria To study: suffering from infertility due to anatomical causes, suffering from infertility due to male causes, suffering from uterine myoma and hydrosalpinx, smoking, drinking alcoholic beverages, suffering from diabetes, suffering from sleep disorders, using complementary and herbal treatments for infertility during 3 months of intervention implementation, surrogacy

Intervention groups

The intervention group followed the educational package of sleep hygiene and diet based on Iranian traditional medicine texts for up to 3 months, and the control group did not receive any intervention.

Main outcome variables

The primary outcomes include the number of eggs, the

number of mature eggs, the number of embryos, the quality of embryos, the rate of conception, the rate of implantation, and the secondary outcomes of studying the rate of spontaneous pregnancy, chemical pregnancy and clinical pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231004059612N1**

Registration date: **2023-10-28, 1402/08/06**

Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**

Update count: **0**

Registration date

2023-10-28, 1402/08/06

Registrant information

Name

fazeleh fazlollahpourrokni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sleep hygiene education and diet based on Persian traditional medicine texts on the results of in vitro fertilization (IVF/ICSI) of infertile women

Public title

The effect of sleep hygiene education and diet based on Persian traditional medicine texts on the results of in vitro fertilization (IVF/ICSI) of infertile women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary or secondary infertile women with ovarian problems or unexplained causes

Exclusion criteria:

Infertility with anatomical or male causes with sleep disorders and diabetes

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking will be done by randomization method. The randomization unit of infertile women is classified into age groups of less than 30, 30 to 34, 35 to 39, and 40 to 45 years, stratified random allocation will be done in each of the age groups. In total, 31 blocks of 4 will be used for allocation. The random allocation process will be done with Random Allocation 2.0 software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of mazandaran University of Medical Sciences

Street address

ساری- میدان معلم- ساختمان شماره 2 دانشگاه علوم پزشکی و خدمات بهداشتی درمانی

City

sari

Province

Mazandaran

Postal code

4848157945

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.MAZUMS.REC.1402.388

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

Primary or secondary infertility of women with ovarian or unexplained causes

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

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

the number of eggs

Timepoint

before the start of the intervention and after the completion of the intervention

Method of measurement

the number of eggs by ultrasound of the ovary

2**Description**

the number of mature eggs

Timepoint

After the intervention

Method of measurement

The number of mature eggs is measured with a stereomicroscope.

3**Description**

the number of embryos

Timepoint

After the intervention

Method of measurement

Morphological examination of the fetus

4

Description

the quality of embryos

Timepoint

After the intervention

Method of measurement

Morphological examination of the fetus

5

Description

the rate of fertilization

Timepoint

after the intervention

Method of measurement

Fertilization rate is the ratio of the number of fertilized eggs to the number of mature eggs

6

Description

the rate of implantation

Timepoint

after the intervention

Method of measurement

the implantation rate is defined as the number of gestational sacs seen in ultrasound divided by the total number of embryos

Secondary outcomes

1

Description

the spontaneous pregnancy rate

Timepoint

after the end of the intervention

Method of measurement

Spontaneous pregnancy rate based on ultrasound

2

Description

chemical pregnancy

Timepoint

after the end of the intervention

Method of measurement

based on quantitative beta test (B-HCG)

3

Description

clinical pregnancy

Timepoint

after the intervention

Method of measurement

Based on ultrasound

Intervention groups

1

Description

Intervention group: Intervention group: For the people of the intervention group, two face-to-face sessions will be held by an expert in traditional Iranian medicine and a researcher. Each meeting will be held for 60 minutes at the Obstetrics and Gynecology Department of Imam Khomeini Hospital (RA) in Sari, in most of 12 groups of 10 people, with an interval of one week from each other (46-48). Most of the PowerPoint content will be presented to the patients. In the first session, recommendations related to lifestyle and health improvement in the area of sleep based on Iranian traditional medicine texts, and in the second session, recommendations related to dietary compliance based on Iranian traditional medicine texts will be presented, and the content package "diet, sleep" And the 147-item standard food frequency questionnaire (Food Frequency Questionnaire) whose validity and reliability have been measured and confirmed with Spearman's correlation coefficient of 0.47-0.69 in research conducted in Iran (51-49) will be presented. Completing the food frequency questionnaire by the patients is to know the type and amount of food consumed by them during the intervention. The control group will receive the usual treatments. The duration of observing the diet and sleep package is three months (19, 31), which begins with the onset of the patient's menstrual period. Individuals will be followed up to implement diets and sleep. The researcher will follow up by phone once a week and in person once a month. At the end of the second month and after two periods of menstruation, the subjects in the study enter the IVF/ICS cycle. Two weeks after IVF, a small B-hcg test is checked to check for chemical pregnancy. If the result of the test is positive, one month later, an ultrasound will be performed by a radiologist to check the fetal heart and clinical pregnancy(52). The follow-up of patients who have a positive clinical pregnancy will be continued by the researcher until the 12th week of pregnancy. At the end of the study, IVF/ICSI success is measured in two groups

Category

Lifestyle

2

Description

Control group: Control group: will not receive any intervention before in vitro fertilization.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز درمان ناباروری بیمارستان امام خمینی (ره) شهرستان ساری

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Mazandaran 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
Mazandaran University of Medical Sciences
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seyede sedighe yousofi
Position

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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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Part of the data, such as the information about the results, can be shared

When the data will become available and for how long

6 months after the publication of the show

To whom data/document is available

For researchers working in academic institutions

Under which criteria data/document could be used

Only researchers who need additional information of this study in their research process.

From where data/document is obtainable

In charge of the project, Dr. Seyede Siedighe Yousefi, dr_ssyosefi@yahoo.com

What processes are involved for a request to access data/document

After the email request for additional information will be answered within a week.

Comments