

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial comparing the effects of diet based on traditional medicine and usual diet on the results of in vitro fertilization for infertile women

Protocol summary

Study aim

the effects of Iranian Traditional Medicine diet on invitro fertilization outcomes

Design

A Randomized Controlled Trial

Settings and conduct

The study was designed as a randomized clinical trial. Participants in the study were referred to Hazrat Zahra infertility treatment center affiliated to Shahrekord University of Medical Sciences. At the beginning of the study, the volunteers were examined by a practitioner to qualify for the study. The control group received routine healthcare and modern dietary recommendations and the intervention group was advised to observe health principles and nutritional recommendations based on ITM sources. Each individual in the intervention group was trained on traditional dietary advices , foods preparation, nutritionally-prohibited foods and essential health recommendations by the researcher. They also received a training guidance text on the above- mentioned points for further self-learning.

Participants/Inclusion and exclusion criteria

The inclusion criteria: infertile women with ovulatory problems or endometriosis or ideopathic infertility, age 20 to 40 years, giving written consent to participate in the study. Women who had infertility with anatomical causes, infertility of their husbands, having uterine myoma or hydrosalpinx, smoking, drinking alcohol, and diabetes mellitus were not included. Exclusion criteria were as follow: lack of interest or cooperation during the study, refusal to go through IVF / ICSI.

Intervention groups

Each individual in the intervention group was trained on traditional dietary advices ,prohibited foods and essential health recommendations.

Main outcome variables

The primary outcomes of the study were the rate of spontaneous pregnancy and clinical pregnancy, and the secondary outcomes included ovum number, mature

ovum number, embryo number, embryo quality, fertilization rate, implantation rate, and chemical pregnancy.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017013032245N2**

Registration date: **2017-03-08, 1395/12/18**

Registration timing: **prospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **1**

Registration date

2017-03-08, 1395/12/18

Registrant information

Name

Zeinab Alibeigi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 9724

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-07-06, 1396/04/15
Actual recruitment start date
2017-04-10, 1396/01/21
Actual recruitment end date
2017-11-20, 1396/08/29
Trial completion date
2018-03-11, 1396/12/20

Scientific title

Clinical trial comparing the effects of diet based on traditional medicine and usual diet on the results of in vitro fertilization for infertile women

Public title

The impact of diet based on Iranian Traditional Medicine on IVF/ICSI outcomes of infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infertile women with ovulatory problems or endometriosis or idiopathic infertility and endometriosis age 20 to 40 years giving written consent to participate in the study no infertility with anatomical causes no infertility of their husbands not having uterine myoma or hydrosalpinx no smoking no alcohol drinking not diabetic

Exclusion criteria:

lack of interest or cooperation during the study, refusal to go through IVF / ICSI.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **124**

Actual sample size reached: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In the order of entry to study based on a permuted blocks of size four, the patients in each four age groups of under 30, 30-34, 35-37, and 38-40 years were randomly assigned to the intervention and control groups. The random allocation sequence was generated by an investigator who was not involved in eliciting data or conducting the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه ع پ ایران

Street address

تهران - بزرگراه همت - جنب برج میلاد - دانشگاه علوم پزشکی ایران

City

تهران

Province

Tehran

Postal code

1449614535

Approval date

2017-01-15, 1395/10/26

Ethics committee reference number

IR.IUMS.REC1395.9221309206

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

clinical pregnancy

Timepoint

3 mounts after intervention

Method of measurement

sonography

Secondary outcomes

1

Description

Oocyt quality

Timepoint

2-3 mounts after intervention

Method of measurement

Oocyt quality evaluation criteria

2

Description

Embryo quality

Timepoint

2-3 mounts after intervention

Method of measurement

Embryo quality evaluation criteria

3

Description

Endometrium tickness

Timepoint

2-3 mounts after intervention

Method of measurement

Sonography

4

Description

Implantation rate

Timepoint

2-3 mounts after intervention

Method of measurement

The number of gestational sac divided by the number of transferred embryos

5

Description

Fertility rate

Timepoint

2-3 mounts after intervention

Method of measurement

the number of oocytes fertilized divided by the number of oocytes inseminated

6

Description

Chemical pregnancy

Timepoint

2-3 mounts after intervention

Method of measurement

Serum B-hCG measurment

Intervention groups

1

Description

Intervention group: Diet based on traditional medicine in the intervention group for 2 to 3 months before IVF/ICSI. The recommended foods are those that help gestation, enhance libido, are semen producer, resolve the liver and spleen obstruction, strengthen uterine and main body organs including the brain, liver and heart and they have been used in infertility treatments. These food choices are derived from traditional medicine literature sources and are recommended to be included in patients' meal plan (breakfast, lunch, dinner and snacks).

Category

Treatment - Other

2

Description

Control group: The usual daily diet in the control group for 2 to 3 months before IVF/ICSI.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Infertility Center of Hazrat Zahra

Full name of responsible person

Maryam Nemati, Gynecologist and infertility specialist

Street address

Infertility Center of Hazrat Zahra, Next to the Imam Hassan mosque, West Saadi Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

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8816866659

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary Medicine (RICM)

Full name of responsible person

Fataneh Hashem Dabaghian

Street address

9, Pirnia Allay, Lalezar Street, Jomhuri Street

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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

Research Institute for Islamic and Complementary
Medicine (RICM)

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of
Medical Sciences

Full name of responsible person

Ali Javad Musavi

Street address

Iran University of Medical Sciences, Besides Milad
Tower, Hemmat Highway, Tehran

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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

Vice Chancellor for research of Iran University of Medical
Sciences

Proportion provided by this source

50

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

Iran University of Medical Science

Full name of responsible person

Zeinab Alibeigi Beni

Position

PhD Student of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Mojgan Tansaz

Position

Traditional Medicine Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Traditional Medicine Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be sent to researchers upon request.

When the data will become available and for how long

After publication the results of study

To whom data/document is available

Researchers

Under which criteria data/document could be used

for systematic or meta-analysis study

From where data/document is obtainable

Dr Mojgan Tansaz tansaz_mojgan@yahoo.com

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

E-mail correspondence with the principle researcher

Comments

There are no patient names in the data file and numerical codes are used to identify them.