

# 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

alibeigibeni.zeinab@gmail.com

##### 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

##### **Postal code**

8816866659

##### **Phone**

+98 38 3222 0478

##### **Fax**

##### **Email**

mertanem@yahoo.co.uk

## **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

114587111

##### **Phone**

+98 21 5563 9724

##### **Email**

fataneh.dabaghian@yahoo.com

#### **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

**City**

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**Province**

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**Postal code**

1449614535

**Phone**

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**Email**

Dr\_moosavi@yahoo.com

**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

**Street address**

School of Traditional Medicine, Behest Street, Vahdat  
Islami Street, Tehran

**City**

Tehran

**Province**

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**Postal code**

-

**Phone**

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**Fax**

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**Email**

alibeigibeni.zeinab@gmail.com

**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

**Street address**

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Opposite, Valiasr Street, Tehran

**City**

Tehran

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Efat Jafari Dehkordi

**Position**

Traditional Medicine Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

School of Traditional Medicine, Behest Street, Vahdat

Islami Street, Tehran

**City**

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**Province**

Tehran

**Postal code**

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**Phone**

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**Email**

efjafari@yahoo.com

**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.