

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation of Impact of Diet Program based on Traditional Medicine on Ovulation and Fertility Rate in Woman with Induction of Ovulation

#### Protocol summary

##### Summary

(1) Aims: The purpose of this study was to investigate the effect of traditional medicine diet on follicular growth and the incidence of pregnancy in women with ovulation induction. (2) Design: this is a semi-experimental study, participants will be divided into 2 groups (intervention group with Training of Diet Program based on Traditional Medicine and Control group without any training ). In this intervention, women trained for ovulation induction based on traditional Iranian medicine that is derived from Iranian traditional medicine sources are taught to coexist with dietary ovulation induction medications and the effect of diet on follicular growth And the occurrence of pregnancy. In this program, the usual regimen is based on the traditional medicine guidelines, with respect to the limb temperament and the proper general temperament for improving ovulation and fertility, in a way that does not contradict modern medicine. The diet is based on traditional Iranian medicine by a traditional medicine specialist and includes the following points: Fat, Macaroni, Macaroni, Lasagna, Pizza, Noodles, Cold Fruits and Vegetables, Mushrooms, Fries, Raw Vegetables, Barley, Fish, Beef, Veal, Sausages, Sausages, Hamburgers, Tuna Fish, Dishes Coffee, Cacao, Confectionery, Candy and Chocolate, Pickles, Chives, Salted, and Seasoned, Canned, Tomato Paste, Sauce, Dairy (Yogurt, Dough, Ice Cream, Whey, Cheese Spices and peppers (except turmeric and salt), drinks (such as industrial juices, soft drinks, delicatessen, bergamot tea). You may prefer lamb or chicken and chicken, soup bread, rice cooked, apples, grapes, olives, dates, figs, bananas, mangoes, cooked vegetables, carrot juice, apple juice, raisins, currants, egg yolks Honey, Olive Oil, Walnuts, and Pistachios Eat more meals but fewer. It is advisable not to eat food for half an hour before the next two hours. The legumes are soaked for 12 hours and then cooked with a little salt or preferably cooked in half of their equivalent of rice. If you are obliged to use dairy products, you can make a cup of hot milk plus a little

sugar or honey or grape juice (or slightly) a day Use pasteurized cheese. (3) How to do: In this semi-experimental study, 60 infertile women with ovarian syndrome are participated. Individuals are divided into two groups of control and intervention, the intervention group receives the face-to-face training and pamphlet diet plan, and observes the diet during 1 to 3 cycles of ovulation stimulation, and the control group has the usual diet. The dietary regimen is monitored by the feed recall questionnaire and analyzed with the software. (4) Inclusion criteria: The lack of physical illness and chronic : no history of mental problems : ovarian factor infertility : cycles of ovulation induction is 1 to 3 : FSH level over IU / L 1 and less than 15. Exclusion criteria: Do not diet for more than 24 consecutive hours : Lack of patient to the ultrasound report (5) Interventions: The effect of a traditional medicine program on follicular growth and the incidence of pregnancy in women with ovulation induction. The food program is a recipes derived from traditional medicine resources by the professor of traditional medicine counseling. (6) Main outcome variables: The main outcome is follicle growth in terms of follicle count and diameter, and measurement of pregnancy by BhCG assay and sonography and observation of fetal heart rate.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081629388N1**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-16, 1396/07/24

##### Registrant information

**Name**  
nasrin jamehbozorg

**Name of organization / entity**  
nivercity of medical science of iran

**Country**  
Iran (Islamic Republic of)

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**Recruitment status**  
**Recruitment complete**

**Funding source**  
Iran University of Medical Sciences.

**Expected recruitment start date**  
2017-04-04, 1396/01/15

**Expected recruitment end date**  
2017-09-06, 1396/06/15

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Impact of Diet Program based on Traditional Medicine on Ovulation and Fertility Rate in Woman with Induction of Ovulation

**Public title**  
Impact of Diet Program based on Traditional Medicine on Ovulation and Fertility Rate in Woman with Induction of Ovulation

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
Inclusion criteria: The lack of physical illness and chronic ; no history of mental problems ; ovarian factor infertility ; cycles of ovulation induction is 1 to 3 ; FSH level over IU / L 1 and less than 15. Exclusion criteria: Do not diet for more than 24 consecutive hours ; Lack of patient to the ultrasound report

**Age**  
From **20 years** old to **35 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

1

**Registry name**  
-

**Secondary trial Id**  
-

**Registration date**  
empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
University of Medical Sciences Iran-Ethics Committee

**Street address**  
Hemat highway

**City**  
Tehran

**Postal code**

**Approval date**  
2016-12-11, 1395/09/21

**Ethics committee reference number**  
IR.IUMS.REC.1395.9311373009

## Health conditions studied

1

**Description of health condition studied**  
infertility

**ICD-10 code**  
N97.0

**ICD-10 code description**  
Female infertility associated with anovulation

## Primary outcomes

1

**Description**  
Growth of follicles

**Timepoint**  
Before the fifteenth day of the menstrual cycle and 3 cycles after intervention

**Method of measurement**  
Sonography

2

**Description**  
pregnancy

**Timepoint**

After the first delay in menstruation (a period of ovulation stimulation is performed in three menstrual cycles, a three-cycle maximum test is performed.)

#### **Method of measurement**

Levels of serum BHCG/Imaging FHR In Ultrasound

#### **Secondary outcomes**

empty

#### **Intervention groups**

##### **1**

#### **Description**

In this intervention, women trained for ovulation induction based on traditional Iranian medicine that is derived from Iranian traditional medicine sources are taught to coexist with dietary ovulation induction medications and the effect of diet on follicular growth And the occurrence of pregnancy. In this program, the usual regimen is based on the traditional medicine guidelines, with respect to the limb temperament and the proper general temperament for improving ovulation and fertility, in a way that does not contradict modern medicine. The diet is based on traditional Iranian medicine by a traditional medicine specialist and includes the following points: Fat, Macaroni, Macaroni, Lasagna, Pizza, Noodles, Cold Fruits and Vegetables, Mushrooms, Fries, Raw Vegetables, Barley, Fish, Beef, Veal, Sausages, Sausages, Hamburgers, Tuna Fish, Dishes Coffee, Cacao, Confectionery, Candy and Chocolate, Pickles, Chives, Salted, and Seasoned, Canned, Tomato Paste, Sauce, Dairy (Yogurt, Dough, Ice Cream, Whey, Cheese Spices and peppers (except turmeric and salt), drinks (such as industrial juices, soft drinks, delicatessen, bergamot tea). You may prefer lamb or chicken and chicken, soup bread, rice cooked, apples, grapes, olives, dates, figs, bananas, mangoes, cooked vegetables, carrot juice, apple juice, raisins, currants, egg yolks Honey, Olive Oil, Walnuts, and Pistachios Eat more meals but fewer. It is advisable not to eat food for half an hour before the next two hours. The legumes are soaked for 12 hours and then cooked with a little salt or preferably cooked in half of their equivalent of rice. If you are obliged to use dairy products, you can make a cup of hot milk plus a little sugar or honey or grape juice (or slightly) a day Use pasteurized cheese

#### **Category**

Lifestyle

##### **2**

#### **Description**

In the control group, the diet program is not taught.

#### **Category**

N/A

#### **Recruitment centers**

##### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Akbar Abadi Hospital

##### **Full name of responsible person**

##### **Street address**

##### **City**

Tehran

#### **Sponsors / Funding sources**

##### **1**

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences.

##### **Full name of responsible person**

Seyed Ali Javad Musavi

##### **Street address**

Iran University of Medical Sciences, Next to Milad tower, Hemmat highway, Tehran.

##### **City**

Tehran

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Iran University of Medical Sciences.

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

#### **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Iran University of Medical Sciences, School of nursing and midwifery

##### **Full name of responsible person**

Nasrin Jamebozorg

##### **Position**

MSc student of Midwifery

##### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Leila Neisani Samani  
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Msc of Midwifery:Academic Degree Instructor  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences, School of nursing and midwifery

### Full name of responsible person

Nasrin Jamebozorg

### Position

MSc student of Midwifery

### Other areas of specialty/work

### Street address

### City

### Postal code

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00

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### Email

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### Web page address

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*