

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

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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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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