

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of traditional medicine products on the success of Intrauterine Insemination (IUI) in infertile women

Protocol summary

Summary

The purpose of this study is to determine the effect of traditional medicine products on the success of Intrauterine Insemination (IUI), and it is a non-randomized clinical trial with a historical control group; not blind; without placebo; Trial phase:1-2;The study population: infertile women referred to Milad infertility center of Mashhad, Inclusion criteria: Age between 20 to 40 years; Infertility due to anovulation, male factor infertility and unexplained infertility; Infertility below 15 years; Sperm count over 5 million; Normal hormone tests, Exclusion criteria :Body Mass Index (BMI) more than 35; Follicle diameter unsuitable for injection of Human Chorionic Gonadotropin (HCG); Endometriosis, Target sample size 432,Both intervention and control groups from 3th to 5th day of menses will be received Clomiphene or letrozole for 5 days and days 6, 7 and 8 of menses Human Menopausal Gonadotropin (HMG) or GONALF will be received. On the ninth day, sonography will be done. If found any follicles more or equal 18 mm at 12 to 14 cycles ,5000 units of HCG will be injected and after 36 hours IUI will be done. Intervention group: From 7th day of menstruation until the day of IUI, Combination products (1%) containing honey and Mace (the dried aril of Myristica fragrans Houtt), will be used into vagina with applicator once per night. Control groups: only IUI will be done without placebo. Primary outcome: Chemical and clinical pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111130827N1**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

Maryam Kavousi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3726 5558

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kavousim921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of traditional medicine products on the success of Intrauterine Insemination (IUI) in infertile women

Public title

The effects of preparations of traditional medicine in infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women candidates for Intrauterine Insemination (IUI) (Infertility due to anovulation, male factor infertility and unexplained infertility) ; All patients are first IUI; Age between 20 and 40 years; Infertility below 15 years; Sperm count over 5 million sperm per milliliter after preparation; Normal hormone tests; The uterus is normal in Hysterosalpingography (HSG) and at least has one open Fallopian tube exclusion criteria: Body Mass Index (BMI) more than 35; Follicle diameter unsuitable for injection of Human Chorionic Gonadotropin (HCG); Endometriosis

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **432**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences, Central Building of Mashhad University of Medical Sciences, Golestan Crossroads, Daneshgah Ave.

City

Mashhad

Postal code

13944-91388

Approval date

2017-01-07, 1395/10/18

Ethics committee reference number

IR.MUMS.REC.1395.487

Health conditions studied

1

Description of health condition studied

Infertility due to anovulation

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2

Description of health condition studied

Infertility due to male factors

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

3

Description of health condition studied

Infertility of women with unknown cause

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

chemical pregnancy

Timepoint

16 days after intrauterine insemination

Method of measurement

Measurement of serum β HCG

2

Description

Clinical pregnancy

Timepoint

6 weeks after intrauterine insemination

Method of measurement

vaginal sonography

Secondary outcomes

1

Description

drugs side effect

Timepoint

daily

Method of measurement

Patient reports

Intervention groups

1

Description

Control groups: Routine care

Category

Treatment - Other

2

Description

Intervention group: From 7th day of menstruation until the day that will be done intrauterine insemination, Combination products (1%) containing honey and myristica fragrans will be used into vagina with applicator once per night.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Centre of milad

Full name of responsible person

Maryam kavousi

Street address

The infertility centre of Milad, beside the Sina hospital, The end of eastern Razi street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Cancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Cancellor for Research, Mashhad University of Medical Sciences, Daneshgah Ave., Golestan Crossroads

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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 Cancellor for Research, Mashhad 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

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Full name of responsible person

Maryam Kavousi

Position

PhD student of Persian and Complementary Medicine

Other areas of specialty/work

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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