

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Myo-inositol on pregnancy success in women with IVF/ICSI cycle

Protocol summary

Study aim

The aim of this study is to determine the effect of Myo - inositol on fertility success in patients with IVF / ICSI cycles.

Design

In this single blinded randomized clinical trial, the researcher goes to the infertility clinic daily. Each patient who has inclusion criteria to enroll in the study is considered as a sample. Samples were divided into 2 groups A and B by computer random selection. Patients were randomly divided into two intervention and control groups based on randomized block method. Total of 50 patients were enrolled.

Settings and conduct

This clinical trial is carried out at the Infertility Clinic of Besat Hospital in Sanandaj. Patients are unaware of how they are grouped and blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study included: Infertility for at least one year, not using contraception, candidates for IVF / ICSI, minimum age of 20 years and a maximum of 40 years, Agonist cycles. Exclusion criteria for the study included: Underlying disease, uterine Anomaly, freeze embryo transfer cycle, history of repeated abortions.

Intervention groups

Administration of 2000 mg Myo-inositol plus 200 mg of folic acid daily to ICSI / IVF candidate patients referring to the Infertility Clinic of Besat Hospital

Main outcome variables

The number of oocytes obtained; the number of embryos formed; the number of clinical pregnancies, Number of preterm births, number of abortions, number of live births

General information

Reason for update

Minor changes related to increasing the number of samples studied, increasing the number of outcomes

studied

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042109N1**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **prospective**

Last update: **2022-08-01, 1401/05/10**

Update count: **4**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Shahin Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Myo-inositol on pregnancy success in women with IVF/ICSI cycle

Public title

The effect of Myo-inositol on pregnancy success

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertility for at least one year Not using contraception
Candidates for IVF / ICSI Minimum age of 20 years and a maximum of 40 years Agonist cycles having a regular menstrual cycle (24-35 days)

Exclusion criteria:

Underlying disease Uterine Anomaly Freeze embryo transfer cycle History of repeated abortions Women with any underlying diseases such as metabolic or endocrine disorders and uterine anomaly

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher goes to the clinic daily. Each patient who has inclusion criteria to enroll in the study is considered as a sample. Samples are divided into 2 groups A and B by computer random selection. Patients are randomly divided into two intervention and control groups based on randomized block method, for example: ABAB / AABB / BBAA.

Blinding (investigator's opinion)

Double blinded

Blinding description

Women in the study and outcome assessors are unaware of how they are grouped. The appearance of the drug will be the same for both intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2018-12-02, 1397/09/11

Ethics committee reference number

IR.MUK.REC.1397.236

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The number and quality of oocytes obtained

Timepoint

Two weeks after the intervention

Method of measurement

Using Sonography

2

Description

Number and quality of embryos formed

Timepoint

Third week after intervention

Method of measurement

Using Sonography

Secondary outcomes

1

Description

Number of clinical pregnancy

Timepoint

Clinical pregnancy was defined as a fetal cardiac activity in the 6th to 7th week of pregnancy.

Method of measurement

Sonography

2

Description

Miscarriage

Timepoint

Pregnancy loss earlier than the 20th week of gestation

Method of measurement

Observation and sonography

3**Description**

Preterm delivery

Timepoint

It was measured during the pregnancy. Definition: Birth of the baby earlier than 37wk of the pregnancy.

Method of measurement

Observation and sonography

4**Description**

Live birth

Timepoint

At the end of pregnancy

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: Administration of 2000 mg myo-inositol plus 200 mg of folic acid daily to ICSI / IVF candidate patients referring to the Infertility Clinic of Besat Hospital since the onset of an agonist cycle or embryo transfer for 2 months

Category

Treatment - Drugs

2**Description**

Control group: Administration of placebo daily to ICSI / IVF candidate patients referring to the Infertility Clinic of Besat Hospital at the onset of an agonist cycle or embryo transfer for 2 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Shahin Abbasi

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Keshavarz St, Besat Hospital, Sanandaj, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research of Kurdistan University of Medical Sciences

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Mozh.zarei@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

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**

Sanandaj University of Medical Sciences

Full name of responsible person

Shahin Abbasi

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fariba Seyedoshohadaie

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data on the primary outcome is for sharing.

When the data will become available and for how long

One year after the publication the data will be available.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Dr. Shahin Abbasi, Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran, Email: s.abbasi@muk.ac.ir

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

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email .

Comments