

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Investigating the effect of magnesium on uterine contractions in woman with repeated implantation failure referred to infertility clinic

Protocol summary

Study aim

Investigating the effect of magnesium in solving the problem of frequent implantation failure in IVF

Design

The samples are selected by easy sampling and then randomly assigned to intervention and control groups by Randomized Allocation method. The estimated sample size is determined with the advice of a statistician and using a formula, taking into account a 10% dropout of 30 people in each group. This study is a double-blind study where the patient and the researcher do not know about the procedure.

Settings and conduct

All women referred to Shahrekord infertility clinic with a history of repeated implantation failure are studied. This study is a double-blind study where the patient and the researcher do not know about the procedure. Medicines will be pre-prepared with labels A and B, which will be delivered to the case and control groups.

Participants/Inclusion and exclusion criteria

women referred to Shahrekord infertility clinic with a history of repeated implantation failure

Intervention groups

For patients in the case group, one magnesium citrate tablet will be prescribed for two months, daily. Then, before the intervention and at intervals of one month and two months (after the start of the drug) ultrasound will be taken and the number of uterine contractions will be checked and recorded for at least 15 minutes. Also, at the mentioned intervals (before the intervention and at intervals of one month and two months later), the level of magnesium in the blood will be measured and recorded with the same kit in the same laboratory. After two months, IVF will be done. After 14 days, BhCG will be measured to measure successful implantation. Then, after one month, ultrasound (again by the researcher) will be performed to confirm the intrauterine pregnancy sac.

Main outcome variables

Magnesium level Number of uterine contractions Study group IVF result

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230304057611N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Maryam Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3322 3883

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eslmaryam@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of magnesium on uterine contractions in woman with repeated implantation failure referred to infertility clinic

Public title

Investigating the effect of magnesium on uterine contractions in woman with repeated implantation failure referred to infertility clinic

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Three unsuccessful IVF attempts (negative BhCG)
Willingness to try next IVF Normal karyotype Normal level of LH, FSH, prolactin and TSH

Exclusion criteria:

Patient's refusal to continue treatment Any sensitivity or intolerance to magnesium Existence of systemic disease affecting infertility Presence of structural disease of the uterus

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher assigns a number to the patients using the random allocation rule method and then puts the cards on which the patient's number is written in an envelope in a shuffle. In this method, according to the size of the sample, two color cards, red and blue or labeled A and B, with the same number equal to the total size of the sample (60) are put inside the envelope, then the qualified people who participants in the study will randomly remove one of the cards from the envelope and according to the researcher's definition, if they pick up the red or A card, they will enter the intervention group (30) and if they pick up the blue or B card, they will enter the control group (30).

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the researcher do not know about the procedure. Medicines will be pre-prepared with labels A and B, which will be categorized and prepared by the statistics consultant and delivered to the case 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 Shahrekord University of Medical Sciences

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Hajar Hospital.,Parastar Ave., Kashani Blvd ., Shahrekord Town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.SKUMS.MRD.REC.1401.064

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Magnesium level

Timepoint

before the intervention and at intervals of one month and two months later

Method of measurement

Lab Kit

Secondary outcomes**1****Description**

IVF result

Timepoint

After 14 days of doing IVF
Method of measurement
BHCG lab kit

Intervention groups

- 1**
Description
Intervention group: One daily magnesium citrate tablet (300 mg, Sajpod company) for two months.
Category
Treatment - Drugs
- 2**
Description
Control group: For the patients of the control group, a placebo pill supplied by the same pill manufacturing company (without any special medicine) will be prescribed for two months.
Category
Placebo
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vcrt@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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

Recruitment centers

- 1**
Recruitment center
Name of recruitment center
Fertility clinic and infertility center Shahrekord
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Sponsors / Funding sources

- 1**
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Shahre-kord University of Medical Sciences
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- Person responsible for scientific inquiries**
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Full name of responsible person
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Position
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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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