

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Investigating of effect indomethacin suppositories on pregnancy outcomes in IVF candidates with a history of more than two failed embryo transfers.

Protocol summary

Study aim

Determination of the effect of indomethacin suppository on pregnancy outcome in IVF candidates with a history of more than two unsuccessful embryo transfers.

Design

In a randomized clinical trial with the parallel control group, double-blind; Phase 2-3, on 120 patients; randomization is performed by using block randomization

Settings and conduct

This is a double-blind, parallel clinical trial that will be conducted on 120 IVF candidate patients at Fatemieh Hospital in Hamedan. The researcher who measures and records the outcomes and the patients who receive the intervention are unaware of the type of intervention, so the study is conducted as a double-blind trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 40 years, a history of at least two unsuccessful embryo transfers, having at least two A-grade embryos, unknown causes of IVF failure, and a body mass index (BMI) less than 30 kg/m².
Exclusion criteria: a history of any sensitivity to NSAIDs, uncontrolled chronic diseases, and prohibition of NSAID use.

Intervention groups

In the intervention group, participants received 100 milligrams of Indomethacin suppository manufactured by Darou Pakhsh-Iran one hour before embryo transfer and 12 hours after the first dose, but the control group does not receive this drug.

Main outcome variables

Determination of chemical and clinical pregnancy in two study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N29**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-15, 1402/09/24

Expected recruitment end date

2024-01-22, 1402/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigating of effect indomethacin suppositories on

pregnancy outcomes in IVF candidates with a history of more than two failed embryo transfers.

Public title

Indomethacin suppositories on pregnancy outcomes in IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 40 years, History of at least two unsuccessful embryo transfers, Having at least two A-grade embryos, unknown causes of IVF failure Unknown causes of IVF failure Body mass index (BMI) less than 30 kg/m²

Exclusion criteria:

History of any sensitivity to NSAIDs, Uncontrolled chronic diseases, Prohibition of NSAID use

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will randomly assign the cases to intervention and control groups. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are removed. The four paper sheets will be then placed back into the container, and this action will be repeated until the sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who examines patients for outcomes is not informed of the allocation of patients to the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Hamadan

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6517838695

Approval date

2023-11-24, 1402/09/03

Ethics committee reference number

IR.UMSHA.REC.1402.558

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 day after embryo transfer

Method of measurement

The B- hCG level is greater than 20 IU/L after 14 days of embryo transfer,

2

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer" in English 1

Method of measurement

The sight of a pregnancy sac accompanied by the fetal heartbeat 4 weeks after embryo transfer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the transfer cycle are

given Suppression (FET long) and then receive 100 mg Indomethacin suppositories made by Darou Pakhsh-Iran one hour before embryo transfer and 12 hours after the first dose. Then both groups continue their transfer medications uniformly according to the protocol, and 14-12 days after the transfer, a pregnancy test is performed. If it is positive, an ultrasound is performed for pregnancy sac and fetal heart at weeks 6 and 8.

Category

Treatment - Drugs

2**Description**

Control group: This group receives the same intervention protocol without receiving indomethacin.

Category

Treatment - Drugs

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

Fatemieh Hospital

Full name of responsible person

Shamim Pilehvari

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Fatemieh Hospital, Pasdaran Ave.

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

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohei

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Shamim Pilehvari

Position

Hamadan

Latest degree

Specialist

Other areas of specialty/work

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Full name of responsible person

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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

There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available