

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of Nifedipine administration before fetus transferring in IVF on the rate of pregnancy in infertile women

Protocol summary

Study aim

Determine the effect of nifedipine administration before embryo transfer on pregnancy rate of patients undergoing IVF.

Design

This is a randomized, double-blind, single-center clinical trial. Two arm parallel-group randomized trial with blinded outcome assessment, Phase 3 on 158 patients.

Settings and conduct

This clinical trial will be carried out on 158 women aged 20-39 years who attended to the Infertility Treatment Center of Arash Women's Hospital, Tehran, Iran. Participants were randomly assigned into 2 groups using block randomization method. Block randomization was conducted using sealed envelope, and the randomization list was prepared by the statistician. In this study, the outcome assessors and our statistician who analyzed the data were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-39 years of age, BMI =18-29 and the American Society Anesthesiologist physical status classification system I. Non-inclusion criteria: women with hypertension, hypotension, abnormal uterine cavity, contraindication for the use of estrogen, progesterone, and Nifedipine, the use of drugs interacted with cytochrome P450 within 3 months before the study, serum follicle-stimulating hormone level > 20 mIU/ml on days 2-4 of the menstrual cycle, and irregular heartbeat.

Intervention groups

Intervention group: intake of oral nifedipine tablets, 20 Mg, 30 minutes before embryo transfer. Control group: No intervention

Main outcome variables

Clinical pregnancy; chemical pregnancy

General information

Reason for update

Mismatch between IRCT and article due to blindness and

randomization, inclusion and exclusion criteria, secondary results and correction of ethic code.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140111016162N3**

Registration date: **2020-06-26, 1399/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-15, 1401/09/24**

Update count: **3**

Registration date

2020-06-26, 1399/04/06

Registrant information

Name

Masoomeh Nataj Majd

Name of organization / entity

Arash Womens Hospital, Tehran Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

hosparash@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2017-09-11, 1396/06/20

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

2020-10-30, 1399/08/09

Scientific title

Assessment of Nifedipine administration before fetus transferring in IVF on the rate of pregnancy in infertile women

Public title

Assessment of nifedipine administration in assisted reproductive technology on the rate of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20-39 years of age Fresh embryo transfer Body mass index :18-29 American Society Anesthesiologist physical status classification system I

Exclusion criteria:

History of hypertension History of hypotension Abnormal uterine cavity Contraindication for the use of Estrogen and Progesterone and Nifedipine Administration of drugs that interact with cytochrome P450 activity including azole antifungals, cimetidine, cyclosporine, erythromycin, quinidine, terfenadine, warfarin, benzodiazepines, flecainide, imipramine, propafenone and theophylline within 3 months prior to study enrollment Serum follicle-stimulating hormone (FSH) level >20mIU/mL on days 2-4 of the menstrual cycle Irregular heart beat

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **158**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

We used balanced block randomization with computer-generated sequence in blocks of 6 to recruit subject in each arm. We used the ratio of 1:1 to allocate subjects in each arm.

Blinding (investigator's opinion)

Double blinded

Blinding description

A randomization list is prepared by the statistician. In this process, randomization control trial medicine was placed in similar packets. The sequence of medicine administration and the list of random allocation were not disclosed to dispensing practitioners. These packets were handed over to the dispensing nurse, who was unaware of the contents of each packet. When the doctor declares the eligibility of patients, the nurse then distributes the packets based on the identification numbering.

Fulfillment of the final data is up to the individual who is unaware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-12-07, 1395/09/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1177

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

Ultrasonography

2

Description

Chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

BHCG test

Secondary outcomes

1

Description

Blood pressure Variation

Timepoint

In three intervals including at the time of anesthesia induction, end of anesthesia, and in recovery time

Method of measurement

With a pressure gauge

2

Description

Implantation rate

Timepoint

In pregnancy

Method of measurement

The implantation rates will be calculated as the number of gestational sacs divided by the number of embryos transferred to the uterus

3

Description

Multiple pregnancy rate

Timepoint

After pregnancy

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: Participants receive oral nifedipine tablets, 20 Mg single dose 30 minutes before embryo transfer.

Category

Treatment - Drugs

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Masoomah Nataj-Majd

Street address

Arash Women's Hospital, Rashid avenue; Resalat highway, Tehranpars

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Tehran

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1653915981

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hosparash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Masoomah Nataj Majd

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masoomeh Nataj Majd

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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