Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of Nifedipine administration before fetus transfering 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)

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+98 21 7771 9922

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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 transfering 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 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
Masoomeh Nataj-Mjd
Street address
Arash Women 's Hospital, Rashid avenue; Resalat highway, Tehranpars
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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
Dr. Mohammad Ali Sahraeeyan
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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
Masoomeh Nataj Majd
Position
Assistant Professor
Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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