Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Effect of Nifedipine Administration Before Embryo Transfer on Pregnancy Rates in ICSI cycles, a double blind control trial study

Protocol summary

Study aim
Effect of Nifedipine Administration Before Embryo Transfer on Pregnancy Rates in ICSI cycles, a double-blind control trial study

Design
Double-blind, randomized Clinical control trial with parallel groups

Settings and conduct
Fatemezahra Infertility and Reproductive Health Research Center, Babol

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18 to 40 with ICSI <38 and ICSI candidate for frozen embryo transfer 2. Typically, higher baseline blood pressure Equal to 60/100 mm Hg before embryo transfer. 3. The serum FSH level is not higher than 14 mli/iu. 4. Patients who have a normal cervix in hysterosalpingography. Those who do not contraindicate the use of nifedipine, such as heart and liver patients 6. Patients who do not have a history of irregular heart rate or who do not consume blood pressure pills. Exclusion criteria 1. Patients who have been taking medication interfered with nifedipine over a month such as benzodiazepines, flecainide, imipramine, propafenone, azole antifungals, cimetidine, cyclosporine, erythromycin, quinidine, terfenadine, warfarin and theophylline. 2. The women who have a blood pressure of 60/100 (mmHg) or less just before the prescribing the medicine.

Intervention groups
100 pills of nifedipine 10 mg are placed in uni-shape capsules. Then, 30 minutes before the embryo transfer, blood pressure is checked for all patients, if the blood pressure is equal to or greater than 60/100 mmHg, the envelopes are opened according to the code and the medicine is given to patients.

Main outcome variables
Effect of Nifedipine Administration Before Embryo Transfer on Pregnancy Rates in ICSI cycles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180417039338N3**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**
Update count: **0**

Registration date
2019-01-26, 1397/11/06

Registrant information

Name
Zahra Basirat

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Nifedipine Administration Before Embryo Transfer on Pregnancy Rates in ICSI cycles, a double blind control trial study

Public title
Nifedipine on Pregnancy Rates in ICSI cycles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1.Women 18-40 yr with BMI<38 undergo ICSI treatment and freeze embryo transfer candidate are participated in this study.2. Blood pressure >= 100/60, 3. FSH <14mli/IU. 4. abnormal uterus in HSG or hystroscopy. 5. who do not contraindicate the use of nifedipine, such as heart and liver 6. Patients who do not have a history of irregular heart rate or who do not use hypotention medication.
Exclusion criteria:
Patients who have been taking medication with nifedipine over a month have interfered with drugs such as benzodiazepines, flecainide, imipramine, propafenone, azole antifungals, cimetidine, cyclosporine, erythromycin, quinidine, terfenadine, warfarin and theophylline. 2.Those who have blood pressure of 60/100 (mmHg) or less before embryo transfer
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
All blocking and random allocation processes are performed by the University's statistics center. The statistician uses the online randomization method and the online Randomization.com site for random block assignment. Ultimately, patients are assigned through methods in two groups according to randomized block-sized numbers with block-8.
Blinding (investigator's opinion)
Double blinded
Blinding description
According to the randomized block list, which is given to the mentioned midwife from the university's statistics center, the prescription of the encoded uni- shape pills is done by her. In the end, the list of demographic characteristics and pregnancy outcomes are collected and recorded by the outcome assessor. Patients, the endometrial monitor responsible, the embryo transfer physician, the ICSI laboratory staff and the outcome assessor are not aware of the patient's allocation. The list is inserted in SPSS by statistics.
Placebo
Not used
Assignment
Parallel
Other design features
The medicine contains 100 pills of nifedipine 10 mg (Tolidaru co.) from the package and both are placed in a uni-shape capsule by data collector. As well as 100 pills of folic acid (Iran Drug Pharmacy), 1mg will also be placed in uni-color capsules. The capsules are then inserted into a small uni-shape zipped bag and placed in the uni- shape pocket according to the code. Then the code list will extinct.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
BaboL university of Medical Science
Street address
Ghanj afrouz ST.
City
Babol
Province
Mazandaran
Postal code
47135-547
Approval date
2018-08-01, 1397/05/10
Ethics committee reference number
IR.mubabol.hri.rec.1397.209

Health conditions studied

1

Description of health condition studied
Recurrent Implantation failure in IVF
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pregnancy rate(hCG>31IU/LI) 12 days following embryo transfer
Timepoint
12 days following embryo transfer
Method of measurement
Blood test, BHCG

Secondary outcomes

1

Description
implantation rate: Gestational sac
Timepoint
in 6 weeks after pregnancy
Method of measurement
vaginal sonography

2

Description
clinical pregnancy, Fetal heart rate observation
Timepoint
6-8 after pregnancy
Method of measurement
vaginal sonography

3

Description
spontaneous abortion
Timepoint
before 20 week pregnancy
Method of measurement
vaginal sonography

4

Description
Complications of pregnancy and infant including multiple or ectopic pregnancy, spotting and vaginal bleeding
Timepoint
in 3 months pregnancy
Method of measurement
vaginal sonography

Intervention groups

1

Description
Intervention group: Intervention group are received Nifedipine Tablet 20 mg for 1/2 hr before embryo transfer
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemezahra infertility and Reproductive Health Research Center, Babol
Full name of responsible person
Masoumeh Golsorkhtabar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Fatemeh
Position
obstetrics and gynecology resident
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
There is no further information
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
Not applicable
Data Dictionary
Not applicable