Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of nifedipine administration on embyro transfer success rate, a Randomized Clinical Trial

Protocol summary

Study aim
Improving success rate of embryo transfer in women with primary or secondary infertility
Design
Double blinded placebo controled randomized clinical trial, parallel groups, randomization by permuted block with 4 &6 block size using "ralloc" module of stata 14 mp software, phase 2 trial on 98 patients.
Settings and conduct
Trial conducted in Akbarabadi hospital IVF center, patients and care providers were blinded. 3 weeks after intervention, transvaginal ultrasound was performed to assess primary outcome.
Participants/Inclusion and exclusion criteria
Inclusion : women aged 18 -40 with primary or secondary imfertility,FET or ET embryo transfer, good quality embryo, three embryo of 2 days age. Exclusion: blood pressure less than 100/60 mmHg, BMI more than 38kg/m2, abnormal uterine cavity, nifedipine contraindication, history of recurrent abortion or implantation failure
Intervention groups
Included patients were administered 10 mg oral nifedipine 30 min before embryo transfer. Control group recieved placebo pill(with same shape to nifedipine) 30 min before embryo transfer
Main outcome variables
Clinical Pregnancy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201129049532N1**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **retrospective**
Last update: **2021-11-21, 1400/08/30**
Update count: **0**
Registration date
2021-11-21, 1400/08/30

Registrant information
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Solmaz Hedayat
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-03-16, 1398/12/26
Expected recruitment end date
2020-06-21, 1399/04/01
Actual recruitment start date
2020-03-16, 1398/12/26
Actual recruitment end date
2020-06-14, 1399/03/25
Trial completion date
2021-03-14, 1399/12/24

Scientific title
Evaluation of nifedipine administration on embyro transfer success rate, a Randomized Clinical Trial

Public title
Evaluation of nifedipine administration on embyro transfer success rate, a Randomized Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Women aged 18-40 with primary or secondary infertility fresh or frozen embryo transfer good embryo quality(based on defined criteria) transfer of 3 embryo of two days age

Exclusion criteria:

Blood pressure less than 100/60mmHg Body mass index > 38 kg/m2 Abnormal uterine cavity(congenital or acquired) Nifedipine contraindications(history of severe allergic reaction, porphyria, severe heart failure) Recurrent implantation failure History of recurrent abortion

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **98**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

One to one permuted block randomization with 4-6 block size. No stratification. Using Stata 14 software (ralloc module)

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinded with enveloped pocket containing allocation groups (A & B). Patients also will be blinded of administered drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committe of Iranuniversity of medical sciences

Street address

Ethics committee, Faculty of medicine, Iran university of medical science, hemmat hw, tehran, iran

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Province

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Postal code

1449614535

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.IUMS.FMD.REC.1398.556

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical Pregnancy

Timepoint

Before intervention and 3 weeks after intervention

Method of measurement

Transvaginal ultrasound and serum Bhcg

Secondary outcomes

1

Description

Live birth, multiple gestation, abortion

Timepoint

3 weeks after intervention, 9 months after intervention if primaryboutcome occured

Method of measurement

Transvaginal ultrasound, successful delivery

Intervention groups

1

Description

Intervention group: 18 - 40 year-old women with primary or secondary infertility, candidate for embryo transfer

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi hospital IVF center

Full name of responsible person

Solmaz Hedayat MD

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Akbarabadi hospital IVF center, Molavi st, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor
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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
Iran 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
Iran University of Medical Sciences
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Position
Resident
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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
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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available