

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of amlodipine on the correction of uterine and endometrial artery pulsatility and resistance index and implantation rate in frozen embryo transfer cycles

Protocol summary

Study aim

Determining the effect of amlodipine on uterine artery pulse index and uterine artery resistance in IVF/ICSI candidate couples

Design

This study is a phase 3 randomized clinical trial on 100 patients.

Settings and conduct

In a randomized controlled clinical trial study into intervention and control groups, the number of 100 infertile couples who meet the inclusion criteria and are candidates for IVF/ICSI treatment at Al-Zahra Hospital in Tabriz. On the first day of the cycle, transvaginal ultrasound is performed to check the Pulsatility Index (PI) and Resistance Index (RI) of the uterine artery. The first cycle monitoring is performed on the 9th to 11th day of the cycle. On the day progesterone is started, transvaginal ultrasound is performed to check uterine artery resistance and uterine artery flow, and we compare the endometrial thickness and blood supply, RI, uterine artery PI and pregnancy results in the group that received amlodipine with the group that did not receive it.

Participants/Inclusion and exclusion criteria

Women aged 18 to 40 with ICSI <38 and ICSI candidate for frozen embryo transfer Typically, higher baseline blood pressure Equal to 60/100 mm Hg before embryo transfer. The serum FSH level is not higher than 14 mli/iu Patients who have a normal uterine cavity in hysterosalpingography Those who do not contraindicate the use of Amlodipine, such as heart and liver patients

Intervention groups

Administration of amlodipine 5 mg once every night with the first cycle monitoring will usually start on day 9-11 of the cycle. The treatment will continue until the pregnancy test is done. If the pregnancy is positive, it will continue for 7 weeks.

Main outcome variables

Pulsatility Index (PI), Resistance Index (RI), Implantation rate, pregnancy outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101227005485N11**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 2879

Email address

navalin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-23, 1401/11/03

Expected recruitment end date

2023-03-23, 1402/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of amlodipine on the correction of uterine and endometrial artery pulsatility and resistance index and implantation rate in frozen embryo transfer cycles

Public title

Effect of amlodipine before embryo transfer on pregnancy rate in ICSI cycles

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 18 to 40 with ICSI <38 and ICSI candidate for frozen embryo transfer Typically, higher baseline blood pressure Equal to 60/100 mm Hg before embryo transfer. The serum FSH level is not higher than 14 mli/iu Patients who have a normal uterine cavity in hysterosalpingography Those who do not contraindicate the use of Amlodipine, such as heart and liver patients Patients who do not have a history of irregular heart rate or who do not consume blood pressure pills.

Exclusion criteria:

Patients who have been taking medication interfered with Amlodipine over a month The women who have a blood pressure of 60/100 (mmHg) or less just before the prescribing the medicine.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Alzahra Hospital, Artesh Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TBZMED.REC.1401.965

Health conditions studied**1****Description of health condition studied**

Repeated implantation failure

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes**1****Description**

Mean Pulsatility index of uterine artery

Timepoint

Before intervention and 2 weeks later

Method of measurement

Doppler sonography of uterine arteries

2**Description**

Mean resistance index of uterine artery

Timepoint

Before intervention and 2 weeks later

Method of measurement

Doppler sonography of uterine arteries

Secondary outcomes**1****Description**

pregnancy rate

Timepoint

12 days following embryo transfer

Method of measurement

Blood test, BHCG

2

Description

implantation rate: Gestational sac

Timepoint

in 6 weeks after pregnancy

Method of measurement

vaginal sonography

Intervention groups

1

Description

Intervention group: Amlodipine 5 mg once every night with the first cycle monitoring will usually start on day 9-11 of the cycle. The treatment will continue until the pregnancy test is done. If the pregnancy is positive, it will continue for 7 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Nazli Navali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Nazli Navali

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Not applicable