Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of amilodipine on the correction of uterine and endometrial artery pulsatility and resistence 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 oucome

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 amilodipine on the correction of uterine and endometrial artery pulsatility and resistence 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
Street address
Alzahra Hospital, Artesh Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
navalin@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Parviz Shahabi
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
3335731348
Phone
+98 41 3335 5921
Email
parvizshahabi@gmail.com
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
Gynecology and Obstetrics
Street address
Alzahra Hospital, South Artesh St.
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
navalin@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Sonia Sadeghpour
Position
Assisted Professor
Latest degree

Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kosar Hospital,Hasani Street
City
Urmia
Province
West Azarbaijan
Postal code
5715859497
Phone
+98 44 3346 5079
Email
sadeghpour.s@umsu.ac.ir

Person responsible for updating data

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
Gynecology and Obstetrics
Street address
Alzahra Hospital, South Artesh St.
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
navalin@tbzmed.ac.ir

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