Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of pravastatin on the prevention of preeclampsia in high-risk pregnant women: arandomized controlled clinical trial

Protocol summary

Study aim
Effects of pravastatin on the prevention of preeclampsia in high-risk pregnant women

Design
This is a clinical trial study with control and intervention groups. The patients will be divided into two groups of 45 people using the random block method. This study is double-blind and has parallel groups.

Settings and conduct
This study will be conducted in Al-Zahra Hospital in Tabriz, in the field of prevention of pre-eclampsia in high-risk pregnant women.Patients will be randomly divided into two equal groups.The control group will receive the routine treatment of pregnancy caregivers, and the intervention group, in addition to the routine treatment, will receive one tablet of 10 mg of paravastatin for 16 weeks.Patients' blood pressure will be measured and recorded regularly at each visit until the end of pregnancy.In this study, the person responsible for measuring and recording blood pressure and the person analyzing the data and assessing the outcome will be blinded to the study.

Participants/Inclusion and exclusion criteria
In this study, women who are considered high-risk pregnancies will be included in the study, and if they have a history of sensitivity to statins, they will be prohibited from entering the study.

Intervention groups
In this study, the control group will receive routine prenatal visit care, and the intervention group will receive one 10 mg tablet of paravastatin for 16 weeks in addition to receiving routine daily treatment.

Main outcome variables
Preeclampsia is the main outcome of this study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121224011862N5**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**

Registration date
2022-08-30, 1401/06/08

Registrant information

Name
Farnaz Sahaf

Name of organization / entity
Women's Reproductive Health Research Center

Country
Iran (Islamic Republic of)

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+98 41 1553 9161

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-01, 1401/06/10

Expected recruitment end date
2023-09-01, 1402/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of pravastatin on the prevention of preeclampsia in high-risk pregnant women: arandomized controlled clinical trial

Public title
Effects of pravastatin on the prevention of preeclampsia in high-risk pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women at high risk for the possibility of preeclampsia Consent to participate in the study Pregnancy age 16 to 20 weeks Having minimum literacy Having a phone number to follow up History of preeclampsia in previous pregnancy In Vitro Fertilization (IVF) Family history of preeclampsia BMI 35 and above Age over 40 years
Exclusion criteria:
Uso de anticoagulantes, excepto aspirina. History of allergy to statins Multiple pregnancy History of thrombophilia Chronic kidney disease Autoimmune disease Cardiovascular diseases Smoking and alcohol consumption
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the inclusion criteria are divided into two intervention groups using simple randomization method.The randomization method used in this study is the use of a table of random numbers.Random number table is a set of numbers that is generated without a specific pattern or order and they generated randomly and they are formed in a table.In first the direction of reading the numbers was specified.To read the numbers, random numbers are read from the left side of the table, then even numbers extracted from the table are allocated to control group and odd numbers extracted from the table are allocated to intervention group .
Blinding (investigator's opinion)
Double blinded
Blinding description
Before prescribing the drug to the patient, the plan is introduced and written consent is received. Study at the outcome assessor level, and statistical analyzer of the results will be blinded.The possibility of blinding the patient and the doctor in order to respect the rights of the patients is not acceptable Because oral parvastatin tablets will be prescribed. The clinical caregiver of the patients, who is responsible for measuring and recording the blood pressure of the patients, will not know whether the patient is in the control or intervention group .Information forms with Group A and Group B headers will be delivered to the statistician for data analysis.The evaluator of the results of the study will also evaluate the groups as A and B and will be unaware of the type of intervention performed for each group.
Placebo
Not used
Assignment
Parallel
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
Third Floor; Central Building of Number2; Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TBZMED.REC.1401.234

Health conditions studied

1

Description of health condition studied
Pre-eclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
preeclampsia
Timepoint
before the intervention (16 weeks of pregnancy), then in the second visit (20 weeks of pregnancy), the third visit (24 weeks of pregnancy), the fourth visit (28 weeks of pregnancy), the fifth visit (30 weeks of pregnancy), sixth visit 32th week of pregnancy), seventh visit (34 th week of pregnancy) and eighth visit (38-40 th week of pregnancy)

Method of measurement
mercury sphygmomanometer with a suitable cuff from the right arm in a sitting position after 15 The minute of rest.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The group receiving routine prenatal care treatment
Category
Treatment - Drugs

2

Description
Intervention group: In addition to receiving routine prenatal care, the intervention group will receive a 10 mg paravastatin (Abourihan Pharmaceutical Company) tablet daily for 16 weeks after diagnosis. The required number of pills will be provided to the participants at each visit until the next visit. To ensure the use of pills, pregnant mothers in the intervention group will be given a checklist to mark the checklist after each use and to avoid daily forgetting of the pill. At the end of each week, participants will be contacted by phone about the correct use of the pills. Participants will be excluded from the study if the pills are taken irregularly.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Farnaz Sahaf
Street address
Alzahra Hospital, South Artesh St.
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Tabriz
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz
Full name of responsible person
Dr.Parviz Shahabi
Street address
No. 2 Central Building,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research,Tabriz
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.Farnaz Sahaf

Position

Associte proffesor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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