Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effect of nifedipine with and without sildenafil citrate on management of preterm labor in pregnant women: a triple-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of nifedipine with and without sildenafil citrate on management of preterm labor in pregnant women

Design
This is a triple-blind randomized clinical trial, phase III, in which 126 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible pregnant women referring to the Fatemieh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be triple-blinded so that neither patients nor the physician examining the patients, and data analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 15 to 45 years, Pregnant women, Gestational age of 24 to 36 weeks. Exclusion criteria: Proven chorioamnionitis, Cervical dilatation more than 4 cm, Rupture of the amniotic sac, Chronic diseases (hypertension, renal failure, diabetes) Tocolytic contraindication, Contraindication of nifedipine or sildenafil, Previous history of preterm labor

Intervention groups
Intervention group: Routine care plus nifedipine tablet (manufacture by Zahravi Pharmaceutical Co.) 20 mg every 8 hours for one day and sildenafil vaginal tablet (manufacture by Pars Darou Pharmaceutical Co.) 25 mg every 8 hours for one day. Control group: Routine care plus nifedipine tablet (manufacture by Zahravi Pharmaceutical Co.) 20 mg every 8 hours for one day.

Main outcome variables
Neonatal birth weight, hospitalization of the neonate in NICU ward

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120215009014N382**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **prospective**

Last update: **2022-05-12, 1401/02/22**
Update count: **1**

Registration date
2021-02-08, 1399/11/20

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-05-21, 1400/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of nifedipine with and without sildenafil citrate on management of preterm labor in pregnant women: a triple-blind randomized clinical trial

Public title
Effect of nifedipine with and without sildenafil citrate on management of preterm labor in pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 15 to 45 years, Pregnant women, Gestational age of 24 to 36 weeks

Exclusion criteria:
Proven chorioamnionitis, Cervical dilatation more than 4 cm, Rupture of the amniotic sac, Chronic diseases (hypertension, renal failure, diabetes) Tocolytic contraindication, Contraindication of nifedipine or sildenafil, Previous history of preterm labor

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple-blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2020-08-22, 1399/06/01

Ethics committee reference number
IR.UMSHA.REC.1399.484

Health conditions studied

1

Description of health condition studied
Preterm labor

ICD-10 code
O60

ICD-10 code description
Preterm labor

Primary outcomes

1

Description
Gestational age

Timepoint
At delivery

Method of measurement
By taking history

2

Description
Neonatal birth weight

Timepoint
At delivery

Method of measurement
by scale

3

Description
Hospitalization of the neonate in NICU ward

Timepoint
After delivery
Method of measurement
Based on the medical record

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care plus nifedipine tablet (manufacture by Zahravi Pharmaceutical Co.) 20 mg every 8 hours for one day and sildenafil vaginal tablet (manufacture by Pars Darou Pharmaceutical Co.) 25 mg every 8 hours for one day
Category
Treatment - Drugs

2

Description
Control group: Routine care plus nifedipine tablet (manufacture by Zahravi Pharmaceutical Co.) 20 mg every 8 hours for one day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Dr. Seyedeh Arezoo Hoseini
Street address
Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Arezoo Hoseini
Position
Resident of Gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific

inquiries

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Name of organization / entity
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Full name of responsible person
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Latest degree
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Person responsible for updating data

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Professor of Epidemiology

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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