

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

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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

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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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Arezoo.hoseini.md@gmail.com

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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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