

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of nifedipine and indomethacin on the number of uterine contractions, CRP and white blood cell count in pregnant women with idiopathic preterm labor

Protocol summary

Study aim

Determining the number of uterine contractions, CRP and white blood cell count in pregnant women with preterm labor in different groups

Design

Randomized double-blind randomized clinical trial on 64 patients (32 in A and 32 in B)

Settings and conduct

After obtaining the code of ethics and the IRCT code and obtaining the informed consent of the patient, he will be referred to the obstetrics and gynecology ward of Imam Sajjad Hospital. Eligible women were then randomly assigned to one of two groups. First, the number of contractions is stabilized by tocography, then the vaginal examination and the extent of dilatation and effusion will be performed by the researcher. Becomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Pregnancy age 26-24 weeks with first trimester ultrasound 2- Contractions with the rotation of four numbers in 20 minutes or eight numbers in 60 minutes 3- Cervical dilatation equal to or more than one centimeter Exclusion criteria: 1- Having chronic diseases such as high blood pressure and diabetes 2- Having autoimmune diseases 3- History of fetal death, multiple births and systemic diseases of the mother

Intervention groups

In the nifedipine group (n = 32) nifedipine capsules 10 mg (one capsule) In indomethacin group (n = 32) Oral capsule 50-mg oral indomethacin

Main outcome variables

Side effects of drugs; Number of uterine contractions; White blood cell count; CRP concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220219054064N1**

Registration date: **2022-03-06, 1400/12/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-06, 1400/12/15**

Update count: **0**

Registration date

2022-03-06, 1400/12/15

Registrant information

Name

erfan zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3235 8756

Email address

lahze007@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-25, 1400/12/06

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nifedipine and indomethacin on the number of uterine contractions, CRP and white blood cell count in

pregnant women with idiopathic preterm labor	
Public title	The effect of nifedipine and indomethacin on pregnant women
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: 26-34 weeks gestational age confirmed by NLO and first trimester ultrasound Contractions of four numbers in 20 minutes or eight in 60 minutes Cervical dilatation equal to or more than 1 cm and cervical effusion 50% or more Exclusion criteria: Inflammatory diseases, autoimmune, infectious, multiple, hypertension, diabetes, cervical insufficiency, bladder rupture, vaginal bleeding, fetal death or fetal malignancy, KWFT, history of trauma, cirrhosis, dilatation, cirrhosis Maternal, known uterine abnormalities (with a history or ultrasound), smoking history, history of taking any medication other than the usual supplements during pregnancy, tuberculosis, intrauterine polycystic ovary syndrome, ulcerative colitis Maternal and fetal HJT, previous tocolytic use in the same pregnancy and mothers for whom continuing pregnancy for medical reasons is dangerous and blood pressure less than 50.90 mm Hg
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	Data analyser
Sample size	Target sample size: 64
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization tool: Due to the small number of samples (32 people in each group), the dice throwing method is used to randomly assign people to two groups. In this way, for each person who enters the clinic or office, he is assigned to one of the treatment groups based on chance. This will continue until the samples are completed in each group.
Blinding (investigator's opinion)	Double blinded
Blinding description	The data analyzer does not know the treatment groups of the study and in the data sent to the analyzer, the names of arbitration A and drug B are used. This study is a blind clinical trial.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

Street address

Shahid Motahari Blvd. - Yasouj University of Medical Sciences

City

Yasouj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2021-09-07, 1400/06/16

Ethics committee reference number

IR.YUMS.REC.1400.188

Health conditions studied

1

Description of health condition studied

Differences in the number of white blood cells

ICD-10 code

D72

ICD-10 code description

Other disorders of white blood cells

2

Description of health condition studied

Elevated C-reactive protein (CRP)

ICD-10 code

R79.82

ICD-10 code description

Elevated C-reactive protein (CRP)

Primary outcomes

1

Description

Reactive Protein Test

Timepoint

The measurement is performed on the first day after delivery.

Method of measurement

Blood test and use of photometric analyzer

2

Description

Number of uterine contractions

Timepoint

In the first 2 hours after administration of the drug, it will be checked every 15 minutes and if controlled, every 4-6 hours.

Method of measurement

See the number of contractions

3**Description**

Number of white blood cells

Timepoint

The first day after delivery

Method of measurement

CBC DIFF

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the indomethacin group (n = 32), 50-mg oral capsules will be administered as the initial dose and then every 50 mg oral capsule every 8 hours for 48 hours, and the maximum dose in 24 hours should not exceed 200 mg. (Country Protocol).

Category

Treatment - Drugs

2**Description**

Intervention group: In the nifedipine group (n = 32), nifedipine 10 mg (one capsule) capsules are given in the first dose, then 20 minutes later, the second dose of 10 mg, then 10 mg every 4 to 6 hours to 48 hours.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Sajjad Hospital, Yasuj

Full name of responsible person

Parvin Alsadat Eslamnik

Street address

Motahhari Blvd., University of Medical Sciences, Vice Chancellor for Education, Research and Technology, First Floor

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Parvin Alsadat Eslamnik

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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

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Erfan zarhe

Position

General Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yasuj - Motahhari Blvd. - University of Medical

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Parvin Alsadat Eslamnik

Position

PhD in Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD in Obstetrics and Gynecology

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Unidentifiable personal data of the study participants will be provided to the Vice Chancellor for Research of Yasouj University of Medical Sciences.

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Only researchers working in academic institutions can apply for the data

Under which criteria data/document could be used

In order to conduct secondary studies

From where data/document is obtainable

Dr. Hossein Mari Ariad oryad.hossein@yums.ac.ir

What processes are involved for a request to access data/document

Official request from the Vice Chancellor for Education, Research and Technology of Yasouj University of Medical Sciences

Comments