Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 tochography, 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
Kohgilouyeh-va-Boyrahmad

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
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 1333 7251
Email
pnghaffari@yahoo.com
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
Street address
Motahhari Blvd., University of Medical Sciences, Vice Chancellor for Education, Research and Technology
City
Yasouj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 1333 7251
Email
pnghaffari@yahoo.com
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

Sciences - Deputy of Education, Research and Technology

City
Yasuje

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 1333 7251

Email
lahze007@gmail.com

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

Street address
Motahhari Blvd., University of Medical Sciences, Vice Chancellor for Education, Research and Technology

City
Yasouj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 3334 6070

Email
pnghaffari@yahoo.com

Person responsible for updating data

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
Ph.D.

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Motahhari Blvd., University of Medical Sciences, Vice Chancellor for Education, Research and Technology

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 1333 7251

Email
pnghaffari@yahoo.com

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