

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study on the efficacy of nifedipine and indomethacin for prevention of preterm birth as monotherapy and combination therapy

Protocol summary

Study aim

To compare the efficacy of two tocolytic agents; nifedipine and indomethacin; for inhibiting preterm uterine contractions as monotherapy and combination therapy.

Design

Randomized double blind clinical trial on 150 pregnant women with spontaneous preterm labor .

Settings and conduct

labor ward of a teaching hospital. Placebo was used for blinding the participants and investigator.

Participants/Inclusion and exclusion criteria

Participants: 150 pregnant women with gestational age of 26-34 weeks of pregnancy with diagnosis of preterm labor and without any conditions that contraindicated for treatment of preterm labor.

Intervention groups

Intervention groups: Group A; 100 mg rectal indomethacin was administered along with an oral placebo. Group B; 20 mg oral nifedipine was administered along with a rectal placebo. Group C; a combination of rectal indomethacin and oral nifedipine was administered.

Main outcome variables

The primary outcome was delivery after 48 hours and deliveries before 34 weeks of gestation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091023002624N26**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **retrospective**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2018-03-25, 1397/01/05

Actual recruitment start date

2016-05-01, 1395/02/12

Actual recruitment end date

2018-03-25, 1397/01/05

Trial completion date

empty

Scientific title

A comparative study on the efficacy of nifedipine and indomethacin for prevention of preterm birth as monotherapy and combination therapy

Public title

Treatment of preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

gestational age of 26 to 34 weeks singleton uterine

contractions with a frequency of at least 4 forceful uterine contractions per 20 minutes or a cervical dilatation of minimum 1 cm and minimum 50% cervical effacement.

Exclusion criteria:

rupture of membrane intrauterine fetal death cervical dilatation of more than 5 cm multiple pregnancy receiving tocolytic within past 24 hours polyhydramnios preeclampsia and eclampsia vaginal bleeding more than bloody show any maternal and fetal condition that contradict with receiving tocolitics severe fetal anomalies contradict fetal life fetal distress

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

simple individual randomization using sealed envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants and the investigators did not know how the patients were allocated to the three groups. The groups were named as A, B and C and placebo were used to blind them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences.

Street address

Hemmat Highway, Chamran Cross.

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311290010

Health conditions studied

1

Description of health condition studied

preterm birth, Preterm delivery, preterm uterine contractions, preterm labor.

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

2

Description of health condition studied

preterm birth, Preterm delivery, preterm uterine contractions, preterm labor.

ICD-10 code

O60.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery

3

Description of health condition studied

preterm birth, Preterm delivery, preterm uterine contractions, preterm labor.

ICD-10 code

O60.0

ICD-10 code description

Preterm labor without delivery

Primary outcomes

1

Description

inhibiting uterine contractions for 48 hours.

Timepoint

48 hours after intervention

Method of measurement

contraction monitoring by tocometer.

2

Description

Delivery before 37 weeks of gestation

Timepoint

Birth date

Method of measurement

Data sheets.

Secondary outcomes

1

Description

Inhibiting the contractions in the first 2 hours after intervention

Timepoint

2 hours after intervention

Method of measurement

Tocometer

2

Description

delivery within 7 days after intervention

Timepoint

7 days after intervention

Method of measurement

Birth date

3

Description

gestational age at the time of birth

Timepoint

time of birth

Method of measurement

birth date

4

Description

duration of prolongation of pregnancy

Timepoint

birth date

Method of measurement

Data sheets

Intervention groups

1

Description

Intervention group: group A; 100 mg rectal indomethacin was administered along with an oral placebo. If the patient responded to the initial treatment after two hours, 25 mg of oral indomethacin was administered every 4 hours plus placebo. The maximum daily dosage of indomethacin was 200 mg/day and the maximum duration of administration was 48 hours.

Category

Treatment - Drugs

2

Description

Intervention group: group B; 20 mg oral nifedipine was administered along with a rectal placebo. After 90 minutes, more 20 mg of oral nifedipine was administered. In case of responding to the initial treatment, 20 mg of oral nifedipine was continued every 3 hours for 72 hours at a maximum dose of 180 mg per day, with a placebo that was given every 4 hours (similar to the indomethacin protocol).

Category

Treatment - Drugs

3

Description

Intervention group: group C; a combination of rectal indomethacin and oral nifedipine was administered per protocol as mentioned above.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Malakouti

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Tehran

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1449614535

Phone

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Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

Private

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**

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Presenting at a paper, congress or seminars.

When the data will become available and for how long

After publication of the paper

To whom data/document is available

Iran University of Medical Sciences

Under which criteria data/document could be used

Permission from Iran University of Medical Sciences

From where data/document is obtainable

From Iran University of Medical Sciences

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

Request from Iran University of Medical Sciences.

Comments