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
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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 envelops.

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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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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
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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