Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

A comparison between nitroglycerin skin patch and nifedipin for the treatment of preterm labbor

Protocol summary

Summary

Normal saline was infused for all women during 30 minutes, and betamethasone was prescribed 12 mg IM, 24 hours apart for 2 doses. The women were randomely divided to 2 groups. 2 groups of women were adjusted according to age.In one group nifedipin and the other group TNG patch(which is a nitric oxide donor and each skin patch contain 10 mg TNG) were used. Blood pressure were monitored every 15 minutes for 1 hour then every 4 houres.First Nitroglycerin patch was removed after 24 houres and the second patch was used for 24 hours. nifedipin (IS A CALCIUM channel blocking agent and each capsule is 10 mg) group: At first, 4 capsules of Nifedipin were prescribed every 20 minutes.Then, for the first 24 hours2 capsules were prescribed every 6 hours, and for the second 24 hours 2 capsules every 8 hours and for the third 24 hours 1 capsul every 6 hours and for the fourth day 1 capsule every 8 hours were prescribed. Response to treatment was defined as arrest of contractions .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108262624N8**
Registration date: **2012-06-05, 1391/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran Univercity of Medical Sciences

Expected recruitment start date

2011-04-03, 1390/01/14

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between nitroglycerin skin patch and nifedipin for the treatment of preterm labbor

Public title

Treatment of preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria

All women who had 4 uterine contractions in 20 minutes or cervical dilatation = 1 cm and effacement = 80% with a gestational age of 26 to 36 weeks were entered the study. Exclusion criteria were: PROM; any maternal or fetal indications for pregnancy termination; IUFD; dilatation of more than 5 cm; allergy to TNG and tocolytic use during previous 24 hours.

Age

No age limit

Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Akbarabadi Hospital, Molavi Street, Molavi cross.
City
Tehran
Postal code
Approval date
2012-04-24, 1391/02/05
Ethics committee reference number
130/2704/90/د

Health conditions studied

1

Description of health condition studied
Preterm labor
ICD-10 code
060-075
ICD-10 code description
Onset (spontaneous) of labour before 37 completed weeks of gestation

Primary outcomes

1

Description
preterm labor
Timepoint
48 hours and 7 days
Method of measurement
delivery

Secondary outcomes

1

Description
adverse effects of drugs
Timepoint
every 15 minutes for 1 hour then every 4 hours
Method of measurement
blood pressure measurement

Intervention groups

1

Description
Nifedipin prescription
Category
Treatment - Drugs

2

Description
TNG skin patch prescription
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Hospital
Full name of responsible person
Maryam Kashanian
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotoohi
Street address
Ghods avenue, Keshavarz cross
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty