Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of transdermal nitroglycerine effect on preterm labor.

Protocol summary

Summary

The aim of present study is to investigation about the "effectiveness of Glyceryl tri nitrate (GTN) patches on preterm labor". This is randomized, single blind, placebo controlled and clinical trial study. Eighty four15_45 years old pregnant women with preterm labor and gestational age between25 and 37 weeks will be randomized to GTN or placebo group. Inclusion criteria: singleton pregnancy with regular uterine contraction. Exclusion criteria: maternal or fetal indication for termination of pregnancy; multiple gestation; premature rupture of membrane(PROM); fetal anomaly; cervical dilatation equal or more than5 cm; sensitivity to nitrates or nitrates contraindication; chorioamnionitis; maternal heart disease; Vasa previa; Placenta previa. After admission and randomization vital signs (maternal blood pressure and maternal heart rate) will be measured. FHR (fetal heart rate) will be monitored for 20 min. Patients will be hydrated with1 liter normal saline, 12 mg Betamethasone will be injected (IM). Then GTN patch or placebo patch will be applied. 1 hour later FHR monitoring, BP and MHR will be assessed. cervical examination will be done, then second patch will be applied. 24 h after randomization the second dose of Betamethasone will be administered and two patches will be removed if uterine contraction continue or cervical dilation progress then two additional patches or placebo will be applied. Finally variables including(no delivery within 24 &48 hour after randomization, number of doses of Betamethasone, complication of drugs and changes of FHR, MHR, MBP before and after patch administration) will be detected and compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108054025N3**
Registration date: **2011-10-26, 1390/08/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-10-26, 1390/08/04

Registrant information

Name

Anisodowleh Nankali

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1427 6310

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Kermanshah University of Medical Sciences.

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of transdermal nitroglycerine effect on preterm labor.

Public title

Investigation of transdermal nitroglycerine effect on preterm labor.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 15 _45 years singleton pregnant women; GA 27_ 35 weeks with painful uterine contractions; equal or more than 4 contractions per 20 min or bishop score equal or more than 3. Exclusion criteria: maternal or fetal indication for termination of pregnancy; multiple gestation; premature rupture of membrane; fetal anomaly; cervical dilatation equal or more than 5 cm; sensitivity to nitrates or nitrates contraindications; chorioamnionitis (maternal fever ,leukocytosis, fetal tachycardia); maternal heart disease; Vasa previa; Placenta previa; vaginal bleeding except bloody show.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Parastar blv, Sorkhehlyjeh, Imam reza hospital.
City
Kermanshah
Postal code
Approval date
2011-07-02, 1390/04/11
Ethics committee reference number
7/420/101

Health conditions studied

1

Description of health condition studied
Preterm labour
ICD-10 code
O60
ICD-10 code description
Preterm labour

Primary outcomes

1

Description
Delivery
Timepoint
24& 48 hour
Method of measurement
Delivery is don or delivery is not done

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
At randomization and 1 h, 24 h& 48 h later
Method of measurement
mmHg

2

Description
Maternal heart rate
Timepoint
At randomization and 1 h, 24 h& 48 h later
Method of measurement
Beat/min

3

Description
Number of doses of corticosteroid .
Timepoint
At randomization and24 h after randomization
Method of measurement
Number

4

Description
Fetal heart rate
Timepoint
At randomization and one hour later
Method of measurement
Beat/min

5

Description
Incidence of complication (headache, vertigo, nausea, vomiting, skin redness, hypo tension)

Timepoint
From randomization till 48 h later.
Method of measurement
it is done or it is not done (patient complaint: headache, vertigo, nausea, vomiting or measured by investigator: skin redness, hypo tension)

6

Description
Change in cervical dilatation.
Timepoint
At randomization and 1 h, 24 h& 48 h later
Method of measurement
cm

Intervention groups

1

Description
Intervention group; 42 pregnant women with diagnosis of preterm labor will be treated by10 mg nitroglycerine patch that will be applied on abdomen. 1 hour later vaginal exam will be done and uterine contractions will be assessed then another patch will be added .24 hour later two patches will be removed, vaginal exam will be done and uterine contractions will be assessed and patch site redness will be checked, if uterine contractions continues or cervical dilation progress then two another patches will be applied. These2 patches also will be removed after48 hours after randomization. If complication such as severe headache or hypo tension will be occurs at any time, patches will be removed.
Category
Treatment - Drugs

2

Description
Control group; 42 pregnant women with diagnosis of preterm labor will be treated by placebo patch that will be applied on abdomen. 1 hour later vaginal exam will be done and uterine contractions will be assessed then another patch will be added .24 hour later two patches will be removed, vaginal exam will be done and uterine contractions will be assessed and patch site redness will be checked if uterine contractions continues or cervical dilation progress then two another patches will be applied. These2 patches also will be removed after48 hours after randomization. If complication such as severe headache or hypo tension will be occurs at any time, patches will be removed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternity research center and Obstetrics & Gynecology Department, Imam Reza Hospital
Full name of responsible person
Parnian Kord Jamshidi
Street address
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Kermanshah University of Medical Sciences.
Full name of responsible person
Farid Najafi
Street address
Building No. 2, Shahid Beheshti blvd.
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Kermanshah 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
Name of organization / entity
Kermanshah University of Medical Sciences.
Full name of responsible person
Parnian Kord Jamshidi
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Resident
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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