

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 four 15_45 years old pregnant women with preterm labor and gestational age between 25 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 than 5 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 with 1 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)

Phone

+98 83 1427 6310

Email address

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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 and 24 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 by 10 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. These 2 patches also will be removed after 48 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. These 2 patches also will be removed after 48 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.

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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

Position

Resident

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

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Full name of responsible person

Sara Daeechin

Position

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Web page address**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