

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

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

#### 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 randomly 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 contains 10 mg TNG) were used. Blood pressure was monitored every 15 minutes for 1 hour then every 4 hours. First Nitroglycerin patch was removed after 24 hours 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 hours 2 capsules were prescribed every 6 hours, and for the second 24 hours 2 capsules every 8 hours and for the third 24 hours 1 capsule 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

###### Name

Maryam Kashanian

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7752 3487

###### Email address

maryamka@iums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Iran University 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 labor

###### 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; IUD; 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/s

**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****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Kashanian

**Position**

Obstetrics &amp; Gynecology, professor

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

Akbarabadi Hospital Molavi street, Molavi cross

**City**

Tehran

**Postal code****Phone**

+98 21 7752 3487

**Fax****Email**

maryamkashanian@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Kashanian

**Position**

Obstetrics &amp; Gynecology

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

Akbarabadi Hospital, Molavi street, Molavi cross

**City**

Tehran

**Postal code****Phone**

+98 21 5563 3244

**Fax****Email**

maryamkashanian@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Kashanian

**Position**

professor of , Department of Obstetrics &amp; Gynecology

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

Akbarabadi Hospital, Molavi street, Molavi cross.

**City**

Tehran

**Postal code****Phone**

+98 21 5563 3244

**Fax****Email****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*