

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of vaginal nitroglycerin versus receiving nothing on cervical dilation in women with post-term pregnancy: a single-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of vaginal nitroglycerin versus receiving nothing on cervical dilation in women with post-term pregnancy

##### Design

This is a single-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible women with post-term pregnancy who will refer to Fatemeh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years Women with post-term pregnancy (gestational age above 40 weeks and 4 days) Nulliparous Singleton Cephalic presentation  
Exclusion criteria: Contraindication of nitroglycerine  
Previous cesarean section or any uterine scar Any chronic disease Vaginal bleeding or drainage  
Oligohydramnios Intrauterine growth restriction (IUGR)

##### Intervention groups

Intervention group: Prenatal routine cares plus vaginal nitroglycerin 40 mcg every 4 hours until three dose  
Control group: Just prenatal routine cares

##### Main outcome variables

Primary outcome: Assessing the duration of time from induction to the active phase of labor  
Assessing the amount of bleeding  
Measuring the neonatal pulse rate  
Measuring the maternal pulse rate  
Secondary outcome: Assessing headache and nausea  
Flushing and changes in blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N282**

Registration date: **2019-05-29, 1398/03/08**

Registration timing: **prospective**

Last update: **2019-05-29, 1398/03/08**

Update count: **0**

##### Registration date

2019-05-29, 1398/03/08

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Effect of vaginal nitroglycerin versus receiving nothing on cervical dilation in women with post-term pregnancy: a single-blind randomized clinical trial

## Public title

Effect of vaginal nitroglycerin versus receiving nothing on cervical dilation in women with post-term pregnancy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 18 to 40 years Women with post-term pregnancy (gestational age above 40 weeks and 4 days) Nulliparous Singleton Cephalic presentation

### Exclusion criteria:

Contraindication of nitroglycerine Previous cesarean section or any uterine scar Any chronic disease Vaginal bleeding or drainage Oligohydramnios Intrauterine growth restriction (IUGR)

## Age

From **18 years** old to **40 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single blind

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

#### Approval date

2019-05-04, 1398/02/14

#### Ethics committee reference number

IR.UMSHA.REC.1398.089

## Health conditions studied

### 1

#### Description of health condition studied

Post-term pregnancy

#### ICD-10 code

O48.0

#### ICD-10 code description

Post-term pregnancy

## Primary outcomes

### 1

#### Description

Assessing the duration of time from induction to active phase of labor

#### Timepoint

12 hours after the intervention

#### Method of measurement

With physical examination

### 2

#### Description

Assessing the amount of bleeding

#### Timepoint

12 hours after the intervention

#### Method of measurement

With physical examination

### 3

#### Description

Measuring the neonatal pulse rate

#### Timepoint

12 hours after the intervention

#### Method of measurement

With physical examination

#### 4

##### **Description**

Measuring the maternal pulse rate

##### **Timepoint**

12 hours after the intervention

##### **Method of measurement**

With physical examination

## **Secondary outcomes**

#### 1

##### **Description**

Assessing headache and nausea

##### **Timepoint**

12 hours after the intervention

##### **Method of measurement**

By history taking

#### 2

##### **Description**

Flushing and changes in blood pressure

##### **Timepoint**

12 hours after the intervention

##### **Method of measurement**

With physical examination

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Prenatal routine cares plus vaginal nitroglycerin 40 mcg every 4 hours until three dose

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Just prenatal routine cares

##### **Category**

N/A

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Fatemieh Hospital in Hamadan City

###### **Full name of responsible person**

Mahboobeh Goodini

###### **Street address**

Fatemieh Hospital, Pasdaran Ave.

###### **City**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838695

###### **Phone**

+98 81 3828 3939

###### **Email**

mahboobeh.goodini@yahoo.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Dr Saeid Bashirian

###### **Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

###### **City**

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###### **Phone**

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###### **Email**

info.research@umsha.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Hamedan University of Medical Sciences

##### **Proportion provided by this source**

100

##### **Public or private sector**

Public

##### **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**

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Mahboobeh Goodini

###### **Position**

Medical Student

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

General Practitioner

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Ahmadi

**Position**

Gynecologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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ahmadi\_1011@yahoo.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Professor of Epidemiology

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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School of Public Health, Hamadan University of

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**Email**

poorolajal@umsha.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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