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 Fatemieh 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)

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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
Wth 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.
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6517838695
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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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

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Person responsible for updating data

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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