Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effect of painless vaginal delivery versus normal vaginal delivery on maternal and neonatal outcomes in pregnant women: a clinical trial

Protocol summary

Summary

Objectives: To assess the effect of painless vaginal delivery versus normal vaginal delivery on maternal and neonatal outcomes in pregnant women. Design: a clinical trial. Setting and conduct: The eligible pregnant refering to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) gestational age of 37 weeks or over; (b) being eligible for vaginal delivery. Exclusion criteria: (a) having diabetes, cardiovascular diseases, or intracranial diseases; (b) having gestational diabetes, preeclampsia, or macrosomia; (c) coagulation disorders; (d) dermal infection on the location of epidural anesthesia; (e) non-treated bacteremia. Intervention group: (a) epidural anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose; (b) spinal anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose; (c) combined anesthesia including epidural anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose and spinal anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose. Control group: Without receiving anesthesia medications. Primary outcome: (a) measuring the duration of the first and second stages of vaginal delivery after intervention using Friedman curve; (b) measuring episiotomy pain 6 and 12 hours after vaginal delivery using visual analog scale (VAS); (c) assessing Apgar score at the first and fifth minutes after birth through physical examination. Secondary outcome: (a) assessing hyperthermia at 4, 8, and 12 hours after vaginal delivery using oral thermometer; (b) assessing headache 12 hours after vaginal delivery using visual analog scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508259014N77**

Registration date: **2015-09-08, 1394/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-08, 1394/06/17

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

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-06-15, 1394/03/25

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of painless vaginal delivery versus normal vaginal delivery on maternal and neonatal outcomes in pregnant

women: a clinical trial

Public title
Effect of painless vaginal delivery versus normal vaginal delivery on maternal and neonatal outcomes in pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: (a) gestational age of 37 weeks or over; (b) being eligible for vaginal delivery. Exclusion criteria: (a) having diabetes, cardiovascular diseases, or intracranial diseases; (b) having gestational diabetes, preeclampsia, or macrosomia; (c) coagulation disorders; (d) dermal infection on the location of epidural anesthesia; (e) non-treated bacteremia.
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **168**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: The eligible pregnant women who are willing to have painless vaginal delivery will be assigned to the intervention group and those women who are not willing to have painless vaginal delivery will be assigned to the control group. Blinding: Not possible.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2015-08-15, 1394/05/24
Ethics committee reference number
IR.UMSHA.REC.1394.269

Health conditions studied

1

Description of health condition studied
Vaginal delivery
ICD-10 code
O66
ICD-10 code description
Other obstructed labour

Primary outcomes

1

Description
measuring the duration of the first and second stages of vaginal delivery
Timepoint
after intervention
Method of measurement
using Friedman curve

2

Description
measuring episiotomy pain
Timepoint
6 and 12 hours after vaginal delivery
Method of measurement
using visual analog scale (VAS)

3

Description
) assessing Apgar score
Timepoint
at the first and fifth minutes after birth
Method of measurement
through physical examination

Secondary outcomes

1

Description
assessing hyperthermia
Timepoint
at 4, 8, and 12 hours after vaginal delivery
Method of measurement
using oral thermometer

2

Description
assessing headache

Timepoint
12 hours after vaginal delivery
Method of measurement
using visual analog scale (VAS)

Intervention groups

1

Description
epidural anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose
Category
Prevention

2

Description
spinal anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose
Category
Treatment - Drugs

3

Description
combined anesthesia including epidural anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose and spinal anesthesia with Marcaine 0.125 mg (manufacture by Astrazenca) single dose
Category
Treatment - Drugs

4

Description
Without receiving anesthesia medications
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Nahid Radnia
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
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 the Technology, Hamadan 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
Fatemieh Hospital
Full name of responsible person
Dr Nahid Radnia
Position
Gynecologist
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
n.radnia@umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemieh Hospital
Full name of responsible person
Dr Nahid Radnia
Position
Gynecologist
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
n.radnia@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
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