Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Physiological Childbirth with Continuous Midwifery Support and Spinal Anesthesia on Labor Pain, Duration, and Mode of Delivery in Primiparous Women: A Quasi-Experimental Study

Protocol summary

Study aim

This study aims to compare the effects of physiological labor with continuous obstetric support and spinal anesthesia on pain intensity, duration of labor, and method of delivery in primiparous women.

Design

This study is a three-group quasi-experimental study with a parallel design on 120 primiparous women. The physiological labor group will be formed non-randomly and based on the availability of trained midwives. Other participants will be allocated to two groups of spinal anesthesia and routine care by block randomization (block of 6) and opaque and coded envelopes. The allocation unit and the study will be conducted in an open manner

Settings and conduct

The study is being conducted at Qaen Martyrs Hospital on 120 primiparous women. The intervention in the physiological labor group includes continuous midwife support. The group receives spinal anesthesia and the control group has routine care. Due to the nature of the interventions, blinding of participants and midwives is not possible, but the statistical consultant is blinded to the groups. Data collectors are also unaware of the study objectives

Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous, age 18-35 years, singleton, gestational age 38-42 weeks, no chronic disease, desire for vaginal delivery, participation in childbirth preparation classes. Exclusion criteria: extreme obesity, spinal disorders, macrosomia, ruptured membranes

Intervention groups

Intervention group 1: Mothers who receive continuous obstetric support from the active phase of labor until birth. Intervention group 2: Mothers who receive spinal anesthesia during the active phase of labor. Control group: Mothers who receive only standard maternity care.

Main outcome variables

The intensity of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220313054270N2**
Registration date: **2026-06-25, 1405/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-25, 1405/04/04**
Update count: **0**

Registration date

2026-06-25, 1405/04/04

Registrant information

Name

mina ghalenovi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Physiological Childbirth with Continuous Midwifery Support and Spinal Anesthesia on Labor Pain, Duration, and Mode of Delivery in Primiparous Women: A Quasi-Experimental Study

Public title

Comparing the effects of midwife-assisted delivery and spinal anesthesia on labor pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women aged 18 to 35 years singleton pregnancies between 38 and 42 weeks gestation no history of infertility or previous cesarean section and no underlying conditions such as gestational diabetes or hypertension. Participants must be willing to have a vaginal birth and attend childbirth preparation classes.

Exclusion criteria:

Maternal coagulation disorders Maternal obesity Maternal spinal deformity Premature rupture of the membranes Fetal macrosomia Diagnosed psychiatric illness in the mother

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants are initially enrolled in the study using convenience sampling. Given that trained midwives providing continuous support are present only on some shifts in the hospital, allocation to the physiological labor group is based on the availability of these trained personnel; therefore, allocation to this group is quasi-experimental. After the physiological labor group sampling is completed, other eligible women are randomly assigned to one of two groups: spinal anesthesia or routine care. A block randomization method with a block size of 6 is used for this purpose. The random sequence is generated by an independent researcher who has no role in the sample recruitment process and outcome assessment, using a random number table. The group allocations are then placed in opaque, sealed, and numbered envelopes sequentially. After reviewing the inclusion criteria and obtaining informed consent, participants are assigned to the study groups based on the sequence of the envelopes. The randomization unit in this study is the individual (participant) and stratified randomization is not used. Allocation concealment is also maintained until the participant enters the study through the use of opaque and sealed envelopes.

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

Ethics committee of Birjand University of Medical Sciences

Street address

Shafa Street

City

Qaen

Province

South Khorasan

Postal code

9717853076

Approval date

2019-04-29, 1398/02/09

Ethics committee reference number

IR.BUMS.REC.1398.005

Health conditions studied

1

Description of health condition studied

Uncomplicated vaginal delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint

Every 30 minutes, from the time of entering the active phase (5–6 cm dilation) to full dilation (10 cm) and the second stage of labor. The average of the recorded scores is calculated and reported for each individual.

Method of measurement

Visual Pain Scale

Secondary outcomes

1

Description
Duration of the first stage of labor (in hours)
Timepoint
Once after the start of the active phase until complete dilation
Method of measurement
Based on partograph and Friedman curve recording

2

Description
Type of delivery (vaginal, vacuum, cesarean section)
Timepoint
After the embryo is expelled
Method of measurement
Patient file

3

Description
Duration of the second stage of labor
Timepoint
From full dilation to expulsion of the fetus (in minutes)
Method of measurement
Once immediately after the baby is born

4

Description
The need for oxytocin administration (the need for oxytocin administration to induce or enhance uterine contractions during labor is recorded and assessed.)
Timepoint
During the labor process until the baby is born.
Method of measurement
Yes / No

5

Description
First-minute Apgar score (The clinical status of the newborn is assessed based on the Apgar score in the first minute after birth.)
Timepoint
One minute after birth.
Method of measurement
Score 0 to 10 (based on the Apgar scale)

6

Description
Fifth-minute Apgar score (The clinical status of the newborn is assessed based on the Apgar score at the fifth minute after birth.)
Timepoint
Five minutes after birth.
Method of measurement
Score 0 to 10 (based on the Apgar scale)

7

Description
Maternal complications (incidence of maternal complications including perineal laceration, postpartum hemorrhage, retained placenta, fever, infection, and other complications related to childbirth are recorded.)
Timepoint
From the start of the intervention until the mother's discharge.
Method of measurement
Yes / No

8

Description
Neonatal complications (the occurrence of neonatal complications including the need for resuscitation, respiratory distress, NICU admission, and other neonatal complications is recorded.)
Timepoint
From birth to discharge.
Method of measurement
Yes / No

Intervention groups

1

Description
Intervention group 1: Physiological delivery with continuous midwife support: Nulliparous women eligible for vaginal delivery receive continuous care and support from a trained midwife from the time they enter the active phase of labor (cervical dilation of 5 to 6 cm) until the end of labor. The intervention includes the constant presence of a midwife with the mother, emotional support and reassurance, training in breathing and relaxation techniques, encouragement to move and change positions, use of a birthing ball to facilitate pelvic movements, and lumbar and sacral massage. All measures are performed according to the hospital's physiological delivery protocol.
Category
Other

2

Description
Intervention Group 2: Spinal Anesthesia Nulliparous women eligible for vaginal delivery in the active phase of labor receive spinal anesthesia by an anesthesiologist. The medication used consists of fentanyl or sufentanil plus 1 to 2 mg of bupivacaine. After anesthesia, the condition of the mother and fetus and vital signs are monitored according to the hospital protocol. (Manufacturer: Caspian Tamin Pharmaceutical Company).
Category
N/A

3

Description
Control group: Routine obstetric care Participants in this group receive standard obstetric care, including admission and documentation, monitoring of maternal vital signs, fetal heart rate monitoring, recording of labor on a partograph, periodic prenatal examinations, routine prenatal education, and other common obstetric care. In this group, continuous obstetric support, use of physiological delivery techniques, and spinal anesthesia are not provided.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Qaen Shohada Hospital

Full name of responsible person
Peyman Malikinejad

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Shafa Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Birjand 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
Birjand University of Medical Sciences

Full name of responsible person
Maryam Katbi

Position
Instructor, Qaen Faculty of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
De-identified datasets including demographic information, primary and secondary outcomes, along with study protocol, informed consent, and questionnaires, are available for sharing. All direct identifiers have been removed prior to sharing. Access to data is available upon reasonable request from the corresponding author and signing of a sharing agreement.

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Access to study data and documentation is available to qualified researchers.

Under which criteria data/document could be used
A written request, along with a proposal and ethics approval, should be sent to the corresponding author and a data sharing agreement signed. Use is permitted solely for non-commercial research and in accordance with the approved proposal, with the commitment to non-reidentification, citation of the original article, and non-sharing with third parties.

From where data/document is obtainable
Dear applicants, please send your application in the following order of priority: 1. Email (first priority): maryam.katebi8244@yahoo.com Maryam Katebi Response within 10 working days 2. Phone (second priority): Qaen Faculty of Medical Sciences (05632531762) Call during office hours (8am-2pm) All applications will be subject to signing a data sharing agreement after initial review by the corresponding author and approval by the university ethics committee.

What processes are involved for a request to access data/document
The applicant sends a written request with a proposal and ethics approval to the corresponding author's email. An initial response will be provided within 10 business days and, if approved, a data sharing agreement will be sent. After the signed agreement is returned, the administrative and ethics process takes 5-7 days. De-identified data will be prepared and sent within 3-5 business days; the entire process takes about 3-4 weeks.

Comments