

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Comparative study of the effect of using lithotomy, squatting and sitting positions in the second stage of physiologic delivery on severity of pain and outcome of childbirth in primiparous women

Protocol summary

Study aim

Determining the effects of squatting, sitting and supine (lithotomy) positions on the severity of pain and duration of latent and active phase of the second stage of labor in primipara women

Design

The clinical trial included two intervention groups and one control groups, with parallel groups, randomized, 96 samples, sampling from 30/11/2010 to 22/09/2011

Settings and conduct

This is a clinical trial conducted on the primiparous women referring to Shahid Beheshti hospital affiliated to Isfahan University of Medical Sciences and Ostad Motahari hospitals affiliated to Jahrom University of Medical Sciences in 2010-2011. Based on the inclusion criteria and obtaining a written consent of the samples about how to do the study, information about pain intensity of the latent and active phase of the second stage of labor, the severity of pain in the third stage of labor, the duration of the latent phase and the active phase of the second stage of labor, the duration of the third stage of labor, perineum status, type and degree of rupture, through the examination and interview were collected. The severity of pain was measured by McGill's visual analogue scale pain. From the beginning of the study, the researcher used a delivery chart or partograph to determine how progress of labor, maternal and fetal health, or any problems that have occurred during the study. In dilatation of 8-9 centimeters and after engagement or zero station and until the end of the second stage of delivery, the mother was placed in the sitting, squatting and lithotomy position. The length of the latent and active phase of the second stage of labor was measured by a kronometer. During the full cervical dilatation, the kronometer was switched on and immediately upon first observation of the first strong contraction and straining kronometer off and again

immediately on and it was shut again When the baby was completely exited, it was extinguished. Thus, the length of the latent and active phase of the second stage would be calculated. In order to determine the amount of bleeding in the first hour after the birth of the baby in all three groups, immediately after the extraction of the baby, one basin was placed under the mother's hips. In the three groups after the extraction of the placenta and its blood completely, the basin was removed and immediately after, the pad which was weighed were placed in the anus and vulva area and if necessary, the pads were replaced. In the next step, the blood inside the basin was transferred to a graded case and then it was measured and recorded. At the end of the first hour after delivery, the pads and gauzes (which were weighed before by using a digital scale) were weighed again and deducted from the previous weight, and the amount of blood was measured in grams, and according to the blood weight (per grams) formula, they were divided by total blood concentration (total blood concentration is 1.06), which resulted in blood volume per cc and it was accumulated with the volume of blood measured in the scaled container and the volume of bleeding in the first hour after delivery was obtained (by cc).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged between 18-35 years old, primiparous women, gestational age between 37 and 41 weeks, women in dilatation 8-9 cm, singleton pregnancy, fetal presentation (head) in the second stage of labor engagement and at least ischial spines is reached, estimated fetal weight is based on Johnson's law between 2,500-4,000 grams, the tendency and readiness for the physiological delivery; Exclusion criteria: Anatomical and skeletal disorders, lack of labor progress in the first stage of labor, rupture of the water bag over 12 hours, weakness and numbness in the legs (in squat position), short Perinea (vaginal insertion distance to the anal inlet less than 3.5 cm), maternal

fatigue at the end of the first stage of labor;

Intervention groups
 Supine (lithotomy) group: Position of lithotomy in the present study was in the way that the mother was in supine position with 30 head elevation and bent knees. Squatting group: In squatting position, the mother was sitting on her feet so that her sole was in touch with the floor and knee joints were higher than the hips. Sitting group: In sitting position the mother sat on labor chair in the way that her lumbar spines were completely strait and the hip and knee joints were at the same level.

Main outcome variables
 The main consequences include the intensity of the latent and active phase of the second stage of labor, duration of latent phase and active phase of the second stage of labor, duration of third stage of labor, volume of bleeding in the first hour after delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038535N3**

Registration date: **2018-02-26, 1396/12/07**

Registration timing: **retrospective**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

Registration date

2018-02-26, 1396/12/07

Registrant information

Name

Mehri Rezaie

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-11-30, 1389/09/09

Expected recruitment end date

2011-09-22, 1390/06/31

Actual recruitment start date

2010-11-30, 1389/09/09

Actual recruitment end date

2011-09-22, 1390/06/31

Trial completion date

empty

Scientific title

Comparative study of the effect of using lithotomy, squatting and sitting positions in the second stage of physiologic delivery on severity of pain and outcome of

childbirth in primiparous women

Public title

The effect of childbirth positions on the severity of labor pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged between 18-35 years old
 Primiparous women Gestational age between 37 and 41 weeks
 Women in dilatation 8-9 cm (active phase of labor phase)
 Singleton pregnancy Fetal presentation (head) in the second stage of labor engagement and at least ischial spines is reached
 Estimated fetal weight is based on Johnson's law between 4,000-2500 grams
 The tendency and readiness for the physiological delivery

Exclusion criteria:

Anatomical and skeletal disorders All that leads to cesarean section
 Lack of labor progress in the first stage of labor by using paratograph form
 Rupture of the water bag over 12 hours
 Weakness and numbness in the legs (in squat position)
 Short Perinea (vaginal insertion distance to the anal inlet less than 3.5 cm)
 Maternal fatigue at the end of the first stage of labor

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: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize in three group every day, the first person in the squatting group, the second person in the sitting position and the third person in lithotomy position were placed

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 Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave., Research Deputy of Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2010-11-03, 1389/08/12

Ethics committee reference number

389292

Health conditions studied

1

Description of health condition studied

Study of the effect of three childbirth positions of squatting, sitting and lithotomy on the severity of labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of labor pain in the latent phase of the second stage of labor

Timepoint

After the intervention and the end of the latent phase of the second stage of labor

Method of measurement

Visual analogue Scale of McGill Pain

2

Description

Severity of labor pain in the active phase of the second stage of labor

Timepoint

After the intervention and the end of the active phase of the second stage of labor

Method of measurement

Visual analogue Scale of McGill Pain

3

Description

Severity of labor pain in the third stage of labor

Timepoint

After the intervention and the end of the third stage of labor

Method of measurement

Visual analogue Scale of McGill Pain

4

Description

Duration of the latent phase of the second stage of labor

Timepoint

After the intervention

Method of measurement

Kronometer

5

Description

Duration of the active phase of the second stage of labor

Timepoint

After the intervention

Method of measurement

Kronometer

6

Description

Duration of the third stage of labor

Timepoint

After the intervention

Method of measurement

Kronometer

Secondary outcomes

1

Description

Volume of bleeding in the first hour after delivery

Timepoint

After the intervention

Method of measurement

Scales, sanitary pad

2

Description

Type and degree of perineal tear

Timepoint

After the intervention and childbirth

Method of measurement

Observation and examination

3

Description

Apgar score of the infant in the first and fifth minutes of birth

Timepoint

After intervention and delivery

Method of measurement

Neonate Apgar Scale

Intervention groups

1

Description

Intervention group: Squatting position

Category

Treatment - Other

2**Description**

Intervention group: Sitting position

Category

Treatment - Other

3**Description**

Control group: Supine position(Lithotomy)

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital in Isfahan

Full name of responsible person

Mehri Rezaie

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2**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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

Esfahan 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**

Jahrom University of Medical Sciences

Full name of responsible person

Mehri Rezaie

Position

Non-faculty midwife

Latest degree

Master

Other areas of specialty/work

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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