

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of lumbar rotation in standing position and pressure on the 6th splenic point in the active phase on pain severity, duration of labor and childbirth experience of nulliparous women

Protocol summary

Study aim

Comparison of the effect of lumbar rotation in standing position and pressure on the 6th splenic point in the active phase on pain severity, duration of labor and childbirth experience of nulliparous women

Design

Random clinical trial with two intervention groups and one control group on 126 nulliparous women. The samples will be randomly divided into three groups.

Settings and conduct

Nulliparous women with inclusion criteria who are admitted to the maternity ward of Bent Al-Hoda Hospital in Bojnourd at a specified time for delivery are randomly assigned to one of the three intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 18-35 years of old : First pregnancy: Gestational age 38-42 weeks, Cephalic presentation: Spontaneous onset of labor pains and dilatation of 4 cm of the cervix when entering the study: Desire and readiness for physiological delivery: No known chronic medical diseases: Fetal health according to ultrasound findings or prenatal tests Exclusion criteria :All mothers who were excluded from labor and natural childbirth due to maternal or fetal causes : Taking painkillers or accelerators of labor during the study: Occurrence of hypertonic uterine contractions: Mother's unwillingness to continue participating in the study

Intervention groups

Rotation of the lumbar in a standing position: in dilatation of 4 cm, she is placed in a standing position and bends forward with the onset of pain and, leaning against the wall, rotates the lumbar for 30 minutes during each contraction; Pressure on 6th splenic point : In 3-4 cm dilatation with the onset of uterine contraction, bilateral pressure is applied in a circular fashion and clockwise with the researcher's thumbs on 6th splenic point ; Control: Routine care is performed.

Main outcome variables

Severity of labor pain; Duration of delivery; Childbirth experience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049699N1**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **prospective**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Elham Shirdel

Name of organization / entity

Country

Iran (Islamic Republic of)

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eshirdel@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lumbar rotation in standing position and pressure on the 6th splenic point in the active phase on pain severity, duration of labor and childbirth experience of nulliparous women

Public title

Comparison of the effect of lumbar rotation in standing position and pressure on the 6th splenic point in the active phase on pain severity, duration of labor and childbirth experience of nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

18-35 years of old First and singleton pregnancy
Gestational age 38-42 weeks, Cephalic presentation
Spontaneous onset of labor pains and dilatation of 4 cm of the cervix when entering the study The estimated weight of the fetus according to Johnson's law is between 2500-4000 grams Desire and readiness for physiological delivery No known chronic medical diseases (Mental disorders, Skeletal and Anatomical disorders, Skin diseases such as Eczema and Inflammation in the area of pressure, High Fever, Phlebitis, Thrombosis) Fetal health according to ultrasound findings or prenatal tests

Exclusion criteria:

All mothers who were excluded from labor and natural childbirth due to maternal or fetal causes such as Abruption, Umbilical cord prolapses, and Fetal distress Taking painkillers or accelerators of labor during the study Occurrence of hypertonic uterine contractions Mother's unwillingness to continue participating in the study

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **126****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling was performed by Permuted block randomization method. Due to the three groups, the study is designed in six order with the letters B, A and C. After selecting a card by someone other than the researcher, the order of the 3 groups is specified and removed from the total number of cards. Card A: Rotation of the back in a standing position (intervention group) Card B: Pressure on the splenic point 6 (intervention group) Card C: (Control group).

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 Tehran University of Medical Sciences

Street address

Room 605, 6th Floor, Tehran University of Medical Sciences Headquarters Building, Intersection of Keshavarz Boulevard and Ghods Street

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.889

Health conditions studied**1****Description of health condition studied**

Severity of labor pain

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Duration of labor

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Childbirth experience

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Severity of labor pain: The amount of labor pain that is expressed by mother and is different in women during labor and its amount is determined only by mother

Timepoint

Before the intervention, immediately after the first and second intervention in each group

Method of measurement

Standard tool for determining pain score based on Analog Visual Scale

2

Description

Duration of active phase: From the beginning of cervical dilatation of 3-6 cm in the presence of uterine contractions to dilatation of 10 cm during labor

Timepoint

From dilatation of 3 to 6 cm to dilatation of 10 cm of the cervix

Method of measurement

With timer seconds

3

Description

Duration of the second stage of labor: The second stage of labor ends with complete dilatation of the cervix beginning with labor and fetal delivery

Timepoint

From complete dilatation of the cervix to delivery and complete removal of the fetus

Method of measurement

With timer seconds

4

Description

Childbirth experience: Pleasant or unpleasant experience for women during pregnancy, labor and childbirth

Timepoint

Within 2 hours after delivery

Method of measurement

Childbirth Experience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rotation of the lumbar in a standing position: in dilatation of 4 cm, she is placed in a standing position and bends forward with the onset of pain and, leaning against the wall, rotates the lumbar for 30 minutes during each contraction.

Category

Behavior

2

Description

Intervention group: Pressure on the 6th splenic point: In 3-4 cm dilatation with the onset of uterine contraction, bilateral pressure is applied in a circular direction and clockwise with the researcher's thumb on the 6th splenic point

Category

Behavior

3

Description

Control group: Routine care is performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bent Al-Huda hospital

Full name of responsible person

Ziba Taghizadeh

Street address

Art Ave, Maternity Crossroads, West Taleghani Ave

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North Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraian

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226, Qods Ave, Keshavarz Blvd

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1419733171

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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

Tehran 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

School of Nursing and Midwifery, Tehran University of Medical Scienc, at the beginning of East Nosrat,Towhid Sq

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Elham Shirdel

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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

No - There is not a plan to make this available