Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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
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: **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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Bojnourd

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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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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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ziba Taghizadeh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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Elham Shirdel

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Student

Latest degree
Bachelor

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Midwifery

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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

No - There is not a plan to make this available