Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of pressure on bile duct 21 on labor pain severity and length of delivery in primiparous women

Protocol summary

Study aim
Investigating the effect of pressure on GB21 on labor pain severity and length of delivery

Design
Clinical trial, community-based, and pragmatic control group, with parallel groups, blind, randomized,

Settings and conduct
Mothers who are admitted to the active phase of labor, selected according to inclosion criteria. After giving explanations to individuals, they are randomly divided into separate rooms. Intervention teams are unaware of how to intervene. How to handle the pain assessment The pain intensity before the intervention, immediately after the intervention, is 30 minutes and 60 minutes after the intervention using a pain reliever. The results are recorded in the checklist and the examination is recorded. although during 3courses in 3-5cm, 6-7cm, and 8-10cm dilatations in first stage of childbirth and duration of delivery stages will measured

Participants/Inclusion and exclusion criteria
Inclusion criteria: primiparous; age18-35 years; cephalic presentation; Gestational age 37-41 weeks; Singleton; ability to read and write; tendency to use analgesia; be in active phase; Exclusion criteria: not having willingness to work with researcher; Conditions lead to cesarean section

Intervention groups
Pressure group on GB 21; Pressure group on shame point; Control group In the pressure group on GB 21, the researcher pushes his right hand over the point. Using pressure during uterine contractions. In the pressure group on the shame point with the conditions, the pressure is applied to theshame point. In the control group, the researcher only performs the necessary measures in labor.

Main outcome variables
Severity of labor pain؛ Satisfaction of the treatment course, length of delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100503003860N34**
Registration date: **2018-04-17, 1397/01/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-04, 1398/09/13**
Update count: **1**

Registration date
2018-04-17, 1397/01/28

Registrant information

Name
Gity Ozgoli

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8820 2512

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gozgoli@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of pressure on bile duct 21 on labor pain severity and length of delivery in primiparous women

Public title
The effect of pressure on bile duct 21 on labor pain severity and length of delivery in primiparous women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Be primiparous cephalic presentation ability to read and write 18-35years Gestational age 37-41 weeks and Singletonage tendency to use analgesia be in active phase

Exclusion criteria:
Do not have to work with a researcher Conditions lead to cesarean section high risk pregnancies skin disorders chronic diseases mental and anatomical disorders

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **174**

Randomization (investigator's opinion)
Randomized

Randomization description
The appointment of individuals in groups was randomized using the RANDOM ALLOCATION SOFTWARE FOR CLINICAL TRIAL software. Using this software, information about the sample number, the number of groups, the groups names will be taken into the data and output software, which includes the list of random groups of the groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, a full description of the research is given to the research units at first, and the patient is given written consent for participation in the study. Then Pregnant mothers are placed in separate rooms to avoid being aware of the intervention. In the control group only routine care is applied

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaee Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.SBMU.PHNM.1395.705

Health conditions studied

1

Description of health condition studied
labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of labor pain

Timepoint
Before the intervention,Immediately after intervention, 30 minutes and 60 minutes after intervention

Method of measurement
Numerical rating scale

2

Description
Length of Delivery

Timepoint
during 3courses in 3-5cm, 6-7cm, and 8-10cm dilatations in first stage

Method of measurement
minutes

Secondary outcomes

1

Description
Mode of delivery

Timepoint
once-after delivery

Method of measurement

Questioner

2

Description
Neonatal Apgar Score
Timepoint
1 and 5 minute after birth
Method of measurement
check list

Intervention groups

1

Description
first Intervention group: In the intervention group with acupressure on the bile duct 21, the pressure was applied for one minute to the desired point during uterine pain and applied for 30 minutes. The severity of pain is measured immediately before intervention, immediately after intervention, 30 minutes and 60 minutes later.Intervention was applied during 3courses in 3-5cm, 6-7cm, and 8-10cm dilatations in first stage of childbirth and duration of delivery stages was measured.
Category
Other

2

Description
Intervention group 2: The second group is pressure on shame point. This point is located between 1 and 2 thumbs from the point of the Gallbladder21 at the outside of the body.the pressure was applied for one minute to the desired point during uterine pain and applied for 30 minutes. The severity of pain is measured immediately before intervention, immediately after intervention, 30 minutes and 60 minutes later.Intervention was applied during 3courses in 3-5cm, 6-7cm, and 8-10cm dilatations in first stage of childbirth and duration of delivery stages was measured
Category
Other

3

Description
Control group: The third group is the control group. This group receives all routine care except for intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofatheh Hospital in Varamin, affiliated to Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamideh Torkiyan
Street address
Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaee Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dept. of Research, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dolatian Mahrokh
Street address
Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaee Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran
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Phone
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Email
mhdolatian@gmail.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dept. of Research, School of Nursing and Midwifery, Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamideh Torkiyan
Position
Graduate Student of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Midwifery Masters Degree
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Shahid Behehshti University of Medical Sciences, Faculty of Nursing and Midwifery, in frint of Shahid Rajaee Heart Hospital, Intersection of Niayesh, Valiasr St. Tehran
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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
Yes - There is 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
Title and more details about the data/document
The results of the study will be divided into two parts: the length of delivery and the severity of pain
When the data will become available and for how long
After publishing the results as an article
To whom data/document is available
Researchers working in academic places
Under which criteria data/document could be used
Respecting copyright and solely in order to help the researcher to conduct his more accurate study

From where data/document is obtainable

correspond email

What processes are involved for a request to access data/document

By sending an email and after reviewing the request, it will be answered in case of discretion

Comments