Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparsion of pressure in the bladder-Gv20 and Gall bladder-GV20 on Intensity Labour Pain and Coping among Primiparturient Women

Protocol summary

Study aim

Comparison of pressure in the bladder points -GV20 and gallbladder-GV20 on the severity of labor pain in primiparous women. 2. Comparison of pressure in the bladder spots -GV20 and gallbladder-GV20 on the coping ability of labor pain in primiparous women.

Design

In this study, 165 nulliparous women refering to Umm Al Binhayn Hospital for delivery were chosen purposefully and randomly divided into three groups: 1 (gallbladder), intervention 2 (bladder) And common care (control).

Settings and conduct

The research units were randomly assigned into intervention1, intervention2 and control groups. The intervention group 1 received pressure on the GV20 and the bladder points (BL5-BL8-BL9), and in the intervention group 2 pressure on the GV20 and the points Gall bladder (GB8-GB16-GB17-GB18). Thus, in the active phase of the labor (5-4 cm dilatation) every point for 60 seconds; and in the intervention group one 4 minutes of pressure and in the intervention group two, 5 minutes of pressure; applied every 30 minutes by the researcher;so that the sum pressure in each of the two intervention groups were 20 minutes (5 cycles in the intervention group 1 and 4 in the intervention group 2). In the latent phase of the second stage of labor, 60 second pressure is applied to each of the points (a pressure cycle). For assessing the progress of labor vaginal examination is performed every 2 hours. The severity of pain and the ability to coping with pain before intervention ;immediately after intervention and half an hour after the intervention, and then every half hour until the end of the second stage of labor, is examined and recorded. To assess the progress of labor, the modified form of the Organization of Health World used.

Participants/Inclusion and exclusion criteria

Entry requirements; Nulliparous, Single pregnancy, Cephalic presentation fetus,The appropriateness of the fetus with the mother's pelvis, Gestational age 37 weeks and more, Estimated fetal weight 4000-2500 grams, Spontaneous onset of labor, Pain intensity at the beginning of the study is a score of 50 and more, Healthy skin is a pressure area. Conditions of failure to enter;Speech-audio problems, Drug Addiction and Drinking, History of referral to psychiatrist or psychologist, Medical disease; obstetric complications, History of operation on the uterus or cervix, Taking the medication within 24 hours prior to onset of labor, Severe anxiety at the start of the study.

Intervention groups

Intervention group 1: Pressure on GV20 and bladder points (BL5-BL8-BL9) Intervention group 2: Pressure on the GV20 and gallbladder points (GB8-GB16-GB17-GB18) Control group: Get regular care

Main outcome variables

The severity of pain; The ability to deal with pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170503033796N2**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date

2018-02-21, 1396/12/02

Registrant information

Name

Elahe Mansouri Ghzelhesari

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

School of Midwifery, Mashhad

Expected recruitment start date

2017-06-06, 1396/03/16

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of pressure in the bladder-Gv20 and Gall bladder-GV20 on Intensity Labour Pain and Coping among Primiparturient Women

Public title

Comparative study of the scalp acupressure on the pain and the ability to cope with pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Muslims and Iran Age from 18 to 35 years old Written Consent Form nulliparous singleton pregnancy cephalic fetal presentation gestational age 37 weeks and more Fit the head of the fetus with the mother's hip fetal weight between 4000-2500 grams Spontaneous onset of labor (5-4 cm dilated with contractions 20 seconds and at least two more within 10 min) healthy skin pressure areas Pain intensity is 50 or more at the start of the study

Exclusion criteria:

Speech-auditory or dialectal problems Drug Addiction, Drinking and Tobacco History of referral to a psychiatrist or psychologist, drug use or hospitalization due to mental illness in the past year Major stress in the last year Cure for medical conditions Decided to cesarean section The presence of midwifery problems History of operation on the uterus or cervix Use of a prescription by a doctor or midwife or herbal medicine within the last 24 hours for the onset of labor pain Oral temperature equal to or greater than 38 ° C Severe anxiety at the start of the study

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: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, each of the units was selected as available and then random allocation (assignment for the three primary patients in 3 groups was randomized and the same order was observed for other patients until the end of the study) in 3 groups of intervention and control they got.

Blinding (investigator's opinion)

Single blinded

Blinding description

With regard to the LDR's rooms, none of the research units were in contact with each other, and thereforethey were not aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

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Unit 1, Ghoreshi building, Daneshgah Street, Mashhad, Khorasan Razavi

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Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUMS.REC.1396.40

Health conditions studied

1

Description of health condition studied

Labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Coping with Labor Pain

Timepoint

Before the intervention and a half hours until delivery

Method of measurement

Observational questionnaire of coping with labor pain

2

Description

Labor pain

Timepoint

Before the intervention and a half hours until delivery

Method of measurement

Visual analog scale pain

Secondary outcomes

1

Description

Labor progress

Timepoint

From the time of admission (5-4Santy dilation of the cervix) until delivery

Method of measurement

Partogragh modified World Health Organization

Intervention groups

1

Description

Intervention group:With each contraction points of GV20-BL5-BL8-BL9 is pressed for 60 seconds (a total of 4 minutes). The compressor was housed half an hour at the beginning of the contraction and in a 4-minute cycle (60 seconds each) for 5 consecutive cycles. In the latent phase of the second stage of labor, with the onset of uterine contraction, a pressure cycle is applied to each of the points.

Category

Treatment - Other

2

Description

Intervention group: With each contraction points of GV20- GB8-GB16-GB17-GB18 is pressed for 60 seconds (a total of 4 minutes). The compressor was housed half an hour at the beginning of the contraction and in a 4-minute cycle (60 seconds each) for4 consecutive cycles. In the latent phase of the second stage of labor, with the onset of uterine contraction, a pressure cycle is applied to each of the points.

Category

Treatment - Other

3

Description

Control group: Caring for the usual maternity ward at U-Al-Banin Hospital includes taking a vegan, helping in changing clothes, bedding, pads, hearing a fetal heart's sound every half hour

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Um Al-Benin Specialized Women's hospital

Full name of responsible person

Masoumeh Mirtaimouri

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Behjat 16, Ayatollah Behjat street, Zarrineh Crossroad, Mashhad, Khorasan Razavi

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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

Mashhad 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

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Full name of responsible person

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Position

Master of Midwifery

Latest degree

Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We do not plan to publish information about the participants

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available