Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The Effect of knee chest Decubitus - position on the length and duration of labor pain in nulliparous women first- women referred to Ayatollah Kashani Hospital in Jiroft

Protocol summary

Study aim
Determining the effect of prostration position on pain and duration of labor

Design
A clinical trial with a control group, without blinding, was randomized and on 80 people, randomization.

Settings and conduct
The maternity ward of Ayatollah Kashani Hospital in Jiroft will be performed. In addition to routine care, in the intervention group, the prostration position will start at the beginning of the active phase in dilatation of 4 cm, alternately in the prostration position until the end of complete cervical dilatation. The pain will be measured and the duration of labor will be assessed based on the partograph form.

Participants/Inclusion and exclusion criteria
Single pregnant women with fetal cephalic screening, term and low-risk pregnancy, no rupture of the amniotic sac for more than 12 hours, spontaneous contractions and 4 cm dilation of the cervix, estimated fetal weight between 4000-2500 g, health proof The fetus will be included in the study based on the ultrasound findings, not attending prenatal classes, not having known chronic diseases, not having mental and anatomical disorders. Criteria for non-inclusion in the study include: use of pain relievers or labor stimulants and withdrawal from labor and natural childbirth such as decolonization, umbilical cord prolapse and fetal distress.

Intervention groups
In the intervention group, the prostration position will start at the beginning of the active phase in dilatation of 4 cm, alternately (every hour, for 15 minutes) in the prostration position until the end of complete dilatation of the cervix, report the severity of pain at the end of complete dilation of the cervix And after the end of uterine contractions, pain will be measured on a visual scale.

Main outcome variables
Pain; duration of labor progression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200415047087N2**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **prospective**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date
2020-08-21, 1399/05/31

Registrant information
Name
sareh mehni
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 34 4331 5306
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2020-10-22, 1399/08/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of knee chest Decubitus - position on the length and duration of labor pain in nulliparous women first- women referred to Ayatollah Kashani Hospital in Jiroft

Public title

Evaluation of the effect of prostration on pain and delivery time

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnant women with fetal cephalic screening, Term and low-risk pregnancies No rupture of the bladder for more than 12 hours Having spontaneous contractions and dilation of 4 cm of the cervix Estimated fetal weight between 4000-2500 grams Evidence of fetal health based on ultrasound findings Not attending childbirth preparation classes No known chronic diseases No mental and anatomical disorders

Exclusion criteria:

Exclude if you use painkillers or labor stimulants Withdrawal from labor and natural childbirth such as decolonization, umbilical cord prolapse and fetal distress

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be placed in groups of two, the first person from the bag that contained balls A, B, C, D, select one of the balls and based on that if the ball A or C comes out in the group Intervention and if the ball B or D is taken out, it is in the control group. One of the advantages of simple randomization is that it is easy to use. In order to keep the number of people in the two groups the same, if people leave the study, the ball of the removed sample is put back in the bag so that the sample size does not decrease

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples will be selected based on inclusion criteria and will be placed in two groups of control and intervention by simple random allocation method; In this way, first the goals of the project for pregnant women are stated and after obtaining written consent and ensuring the confidentiality of their patients' information, the samples will be placed in groups of two, the first person inside the bag containing balls A, B, C was D, select one of the balls and according to it, if ball A or C is taken out, it is in the intervention group and if ball B or D is taken out, it is placed in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of jiroft University of Medical Sciences

Street address

Imam Reza blv, Sabzevaran Square, Vice Chancellor for Education, Jiroft University of Medical Sciences

City

Jiroft

Province

Kerman

Postal code

7861763730

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.JMU.REC.1398.066

Health conditions studied

1

Description of health condition studied

Duration of labor and pain intensity in nulliparous women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity: The score that a person expresses according to the visual scale of pain, the intensity of her pain

Timepoint

Measure the severity of pain twice: before the intervention and after the intervention

Method of measurement

By asking the mother and using the visual pain scale

2

Description

Duration of labor: Based on the standard partograph form in the women's file, the progress and duration of labor are determined.

Timepoint
After the intervention

Method of measurement
Partograph form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the usual care, in the intervention group, the prostration position will start at the beginning of the active phase in dilatation of 4 cm. Alternately (every hour, for 15 minutes) they will be in the prostration position until the end of complete cervical dilatation.

Category
Other

2

Description
Control group: receive only routine care during labor

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani hospital

Full name of responsible person
Sareh Mehni

Street address
Nurse Street, Kashani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jeeroft 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
Jeeroft 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
Jeeroft University of Medical Sciences

Full name of responsible person
Sareh Mehni

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Midwifery

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Position
Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After completing the data collection and after analyzing the information related to the main variables of the study, they will be published in the form of a report on the end of the project and the article.

When the data will become available and for how long
After the article is published and as long as the article is online

To whom data/document is available
The data published in the form of an article will be accessible to anyone who searches for the article.

Under which criteria data/document could be used
In order to increase the information in the field of midwifery care during labor and in the form of a printed article, the data will be usable

From where data/document is obtainable
To the site of the journal where the article will be published

What processes are involved for a request to access data/document
Search databases and find a published article from this study

Comments