Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of birth ball and supportive method on labor pain

Protocol summary

Summary

1) Objective: To determine and Comparison the effect of birth ball and supportive method on labor pain in pregnant women admitted at the physiologic unite of Assali Hospital Khoramabad . 2) Study Design: A randomized controlled trial. 3) Participants in the study inclusion criteria: A person's consent for entry into the study, participated serving an eight sessions classes, physiological childbirth preparation, aged between 35-18 ,gestational age 42-37;primiparous, Presentations cephalic, singleton pregnancy, dilation 3 -4 cm, low-risk pregnancies; Exclusion criteria: Drug addiction, use of sedative and narcotic drugs, use of oxytocin to induce and augmentations of labor, the delivery of mental and medical obstetric disorders, CPD and the lack of progress. 4) Sample size: 93 people in three groups: Birth ball, support and routine vaginal birth (control), 5) Intervention: In all groups, during cervical dilatation 3-4 cm, 7-5 cm and 10-8 cm pain test is measured. In birth ball group during three phases of cervical dilatation during labor to parturient 30 minutes sitting on birth ball 90 degrees pelvic to rocking moves left and right forward and hind ward. In support group to help the researcher during three phases of cervical dilatation by talking with psychological support will associated him for 30 minutes. In control group receive routine care and standard care without any intervention. In all of them groups, Pain intensity with Visual Analog Scale and behavioral pain in cervix dilatations of 3-4, 5-7 and 8-10 centimeter is measured. One time in each period. Intervention time: 90 minutes 7) Main outcome measures: Pain intensity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208053081N2**
Registration date: **2013-02-25, 1391/12/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

Name
Parvin Asti
Name of organization / entity
Lorestan University Of Medical Seinces
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Loreastan University Of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2015-02-10, 1393/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of birth ball and supportive method on labor pain

Public title

The effect of birth ball and supportive method on labor pain

Purpose

Prevention

Inclusion/Exclusion criteria
inclusion criteria: A person's consent for entry into the study; participated serving an eight sessions classes; physiological childbirth preparation; aged between 35-18;gestational age 42-37;primiparous; Presentations cephalic; singleton pregnancy; dilation 3 -4 cm; low-risk pregnancies; Exclusion criteria: Drug addiction; use of sedative and narcotic drugs; use of oxytocin to induce and augmentations of labor; the delivery of mental and medical obstetric disorders;CPD and the lack of progress.

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: **93**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Country Committee for Medical Research Ethics

Street address
Azadi St., Avesta Park Ave, Vice Chancellor for Research and Technology of the Ministry of Health, Fifth Floor

City
Teharan

Postal code

Approval date
2011-03-14, 1389/12/23

Ethics committee reference number
55/1-ك90پ

Health conditions studied

1

Description of health condition studied
labor pain in active phase

ICD-10 code
000-099

ICD-10 code description
Pregnancy,childbrith and the pureperium

Primary outcomes

1

Description
Intensity of labor pain

Timepoint
During cervix dilatations of 3-4, 5-7 and 8-10 centimeter, one time

Method of measurement
Visual Analog Scale and Present Behavioral Intensity

Secondary outcomes

1

Description
Duration of the phase active of labor

Timepoint
From cervical dilatation (3-4 Cm) to full dilatation

Method of measurement
labor time in hour

Intervention groups

1

Description
In control group receive routine care and standard care without any intervention. Pain intensity with Visual Analog Scale and behavioral pain in cervix dilatations of 3-4, 5-7 and 8-10 centimeter is measured. One time in each period.

Category
Prevention

2

Description
Birth ball ntervention1: In birth ball group during three phases of cervical dilatation during labor to parturient 30 minutes sitting on birth ball 90 degrees pelvic to rocking moves left and right forward and hind ward. Pain intensity with Visual Analog Scale and behavioral pain in cervix dilatations of 3-4, 5-7 and 8-10 centimeter is measured. One time in each period.

Category
Prevention

3

Description
In support group to help the researcher during three phases of cervical dilatation by talking with psychological support will associated him for 30 minutes. Pain intensity with Visual Analog Scale and behavioral pain in cervix dilatations of 3-4, 5-7 and 8-10 centimeter is measured.

One time in each period.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Asali Hospital related to Lorestan University Of Medical Sciences

Full name of responsible person

Parvin Asti

Street address

Midwifery Department ,Nursing and Midwifery Faculty , Lorestan University Of Medical Sciences, Kamalvakd

City

Khoramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research Loreastan University Of Medical Sciences

Full name of responsible person

Mohammad Hassan Kaedi

Street address

Vice Chancellor For Research Loreastan University Of Medical Sciences ,Kamalvand

City

Khoramabad

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor For Research Loreastan University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Lorestan University Of Medical Sciences

Full name of responsible person

Parvin Asti

Position

Master of Midwifery, Faculty member of Lorestan Of Medical Sciences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty