Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of doula supporting on the severity of pain and duration of active phase of labor in primiparous women

Protocol summary

Summary

This study was conducted to determine the effect of Doula on the severity of labor pains on primiparous women who were selected using simple random sampling and randomly divided into two groups of with doula and control group .Inclusion criteria were 18-34 years old, dilatation of cervix 4 cm and gestationl age between 38-42 week . exclusion criteria were psychological disorder, diabetes, hypertension. In this clinical trial study were selected 150 primiparous women who were hospitalized in labor centers and hospitals of zahedan.The severity of pain was measured at the beginning of active phase in the 4 cm and ended of active phase in the 10 cm cervical dilatation by means of Visual Analogue Scale. Duration of active phase and second stage and type of delivery were investigated

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111156242N2**
Registration date: **2012-03-13, 1390/12/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-13, 1390/12/23

Registrant information

Name
Ameneh safarzadeh
Name of organization / entity
Zahedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences.

Expected recruitment start date

2007-07-03, 1386/04/12

Expected recruitment end date

2009-02-15, 1387/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of doula supporting on the severity of pain and duration of active phase of labor in primiparous women

Public title

The effects Doula supporting on severity of labor pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: average 18-34 years; gestational age of 38-42 weeks; cephalic presentation; in active phase (4 cm of cervical dilatation) ; Exclusion Criteria: up or down age with 18-34; Gestational age of up to 42 week or down of 38 week; twin pregnancy, breech presentation, latent phase

Age

From **18 years** old to **34 years** old

Gender

Female

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **150**
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
Ethics Committee of Zahedan University of Medical Sciences
Street address
Pardis Complex; Hesabi Squre; zahedan
City
Zahedan
Postal code
Approval date
2012-01-15, 1390/10/25
Ethics committee reference number
856

Health conditions studied

1

Description of health condition studied
labor
ICD-10 code
080.9
ICD-10 code description
spontaneous delivery,Single unspecified

Primary outcomes

1

Description
Pain Intensity
Timepoint
Initiation of active phase and end of active phase
Method of measurement
Visual Analogue Scale

2

Description
lenght of active phase
Timepoint
durind of first stage of labor
Method of measurement
chart of time by reasercher

Secondary outcomes

1

Description
Duration of second stage of labor
Timepoint
second stage of labor
Method of measurement
chart of time by researcher

Intervention groups

1

Description
Effect of doula in labor pain of doula group
Category
Treatment - Other

2

Description
Standard Care in control group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternity Care of Mirjaveh
Full name of responsible person
Ameneh Safarzadeh
Street address
City
Mirjaveh

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Taheri
Street address
Pardis Complex, Hesabi Square, Zahedan
City
Zahedan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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

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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