Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of the presence of support person and routine intervention for women during childbirth in Isfahan, Iran: A randomized controlled trial

Protocol summary

Summary

In this interventional study, 100 pregnant women will be enrolled. Inclusion criteria are: 1. Singleton normal full-term pregnancy and desire to have natural vaginal delivery, 2. 38-42 weeks of gestation, 3. Spontaneous onset of labor and normal birth with no special procedures or consultation, 4. Family member or a female friend was available to stay in the hospital throughout the birth process. Exclusion criteria are: 1. Chose a caesarean section, 2. Cervical dilatation of more than four centimeters at the time of admission. Eligible patients will be randomly divided into two 50-member groups. Group 1 will be received routine intervention with a support person during labor. Group 2 will be received routine intervention without support person during labor. Patients and support persons will be informed about labor process. The support persons will be guided to support the laboring woman. A support person will be defined as a person, such as mother, sister, or friend, who the patient wants present with her in the delivery room. The role of the support person in labor includes provision of continuous presence, reassurance and praise, comforting touch, massage, warm baths/showers, and overall continuous labor support from their birth partner until the end of the first stage, and continued to receive help throughout the second stages of labor. Data collection include the sociodemographic, length of stage of labor, the cervical laceration, pain before and after labor and satisfaction with labor experience.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111710297N3**
Registration date: **2013-11-25, 1392/09/04**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-11-25, 1392/09/04

Registrant information

Name
Leili Allahbakhshian
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1668 7079
Email address
allahbakhshian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the presence of support person and routine intervention for women during childbirth in Isfahan, Iran: A randomized controlled trial

Public title

Effect of the presence of support person and routine intervention for women during childbirth in Isfahan, Iran: A randomized controlled trial

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Singleton normal full-term pregnancy and desire to have natural vaginal delivery, 38 to 42 weeks of gestation, spontaneous onset of labor and normal birth with no special procedures or consultation, family or a female friend was available to stay in the hospital throughout the birth process. Exclusion criteria: Chose a caesarean section, cervical dilatation of more than four centimeters at the time of admission.
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: **100**
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 Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Postal code
Approval date
2012-02-15, 1390/11/26
Ethics committee reference number
391023

Health conditions studied

1

Description of health condition studied
labor
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Length of stage of labor
Timepoint
During intervention
Method of measurement
Time of cervical dilation

2

Description
Cervical laceration
Timepoint
After intervention
Method of measurement
Yes / No

3

Description
Pain
Timepoint
Before and after intervention
Method of measurement
The numeric rating scale, between 0 (no pain) and 10 (worst pain)

Secondary outcomes

1

Description
Satisfaction
Timepoint
After intervention
Method of measurement
The numeric rating scale (between 0 and 100)

Intervention groups

1

Description
Intervention group received routine intervention with a support person during labor. Routine intervention will be included monitoring of uterine contractions, bleeding, fetal medicals care and other usual hospitals' medical cares. Also, role of the support person will be included includes provision of continuous presence, reassurance and praise, comforting touch, massage, warm baths/showers, and overall continuous labor support from their birth partner until the end of the first stage, and overall continuous labor support from patient during labor.
Category

Other

2

Description
Control group received routine intervention without a support person during labor. monitoring of uterine contractions, bleeding, fetal medicals care and other usual hospitals' medical cares and other interventions will be done by a member of the health team in care of the patient in labor.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person
Zahra Shahshahan

Street address
Shahid Beheshti hospital, Ostad Motahari St., Felezi Bridge, Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of medical sciences

Full name of responsible person
Peyman Adibi

Street address
Deputy of research, Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City
Isfahan

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, Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Zahra Shahshahan

Position
Associate professor

Other areas of specialty/work

Street address
Shahid Beheshti hospital, Ostad Motahari St., Felezi Bridge, Isfahan, Iran

City
Isfahan

Postal code

Phone
+98 31 1334 6340

Fax

Email
shahshahan@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Zahra Shahshahan

Position
Associate professor

Other areas of specialty/work

Street address
Shahid Beheshti hospital, Ostad Motahari St., Felezi Bridge, Isfahan, Iran

City
Isfahan

Postal code

Phone
+98 31 1334 6340

Fax

Email
shahshahan@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Shaghyegh Mashoori

Position

Other areas of specialty/work

Street address
Shahid Behesht hospital, Ostad Motahari St., Felezi Bridge, Isfahan, Iran.

City

Isfahan

Postal code

Phone

+98 31 1334 6340

Fax

Email

smashoori@yahoo.com

Web page address

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