

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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