

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of doula supportive care and acupressure (point BL32) on maternal anxiety and obstetric outcomes

Protocol summary

Summary

This study is a randomized clinical trial on 150 pregnant women had referred to Shoushtari hospital, Shiraz, Iran, and compares the effect of doula supportive care and acupressure (point BL32) on maternal anxiety and obstetric outcomes. After obtaining informed consent, the eligible women were allocated randomly into three groups (two experimental groups and one control group). Spielberger's test was used to measure anxiety in the three groups. In the first group, the researcher as the doula was beside the mother from her entrance into the department. She reassured the mother, encouraged her, and gave her activity and relaxing positions at different stages of labor. In the second group, in 3-4 and 7-8cm dilatation, the mother was placed in a proper position and BL32 point was pressed. The pressure was continuously and gently applied by both thumbs for 20 minutes. It was applied by the beginning and stopped at the end of the contractions. On the other hand, the control group only received the department's routine care. Birth outcomes in three groups studied.

General information

Acronym

point BL32: bladder 32

IRCT registration information

IRCT registration number: **IRCT2013081411706N4**

Registration date: **2013-09-01, 1392/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-01, 1392/06/10

Registrant information

Name

Zahra Masoudi

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2013-02-03, 1391/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of doula supportive care and acupressure (point BL32) on maternal anxiety and obstetric outcomes

Public title

The effect of doula supportive care and acupressure (point BL32) on maternal anxiety and obstetric outcomes

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria of the study: first or second pregnancy; single; term pregnancy; vertex presentation; spontaneous beginning of the delivery process; 3-4 cm cervical dilatation; being 18-35 years old; and having at least middle school degree. The exclusion criteria of the

study were suffering from any physical or mental problems; oligohydramnios; preeclampsia; Rh incompatibility; having a history of smoking; thick meconium and maternal diabetes.

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: **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 in Medical Research, Shiraz University of Medical Sciences

Street address

Research_seven floors_University of Central Building_ near red crescent_ zand avenue_Shiraz

City

Shiraz

Postal code

71345-1978

Approval date

2012-12-05, 1391/09/15

Ethics committee reference number

CT-91-6356

Health conditions studied

1

Description of health condition studied

Mother anxiety

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger questionnaire

2

Description

Duration of the first and second stage of labor

Timepoint

During the intervention

Method of measurement

Per minute

Secondary outcomes

empty

Intervention groups

1

Description

In the first group, the researcher as the doula was beside the mother from her entrance into the department. She reassured the mother, encouraged her, and gave her activity and relaxing positions at different stages of labor.

Category

Treatment - Other

2

Description

In the second group, in 3-4 and 7-8cm dilatation, the mother was placed in a proper position and BL32 point was pressed. The pressure was continuously and gently applied by both thumbs for 20 minutes. It was applied by the beginning and stopped at the end of the contractions

Category

Treatment - Other

3

Description

the control group only received the department's routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shushtari Hospital
Full name of responsible person
andishe jorkesh
Street address
Corner Regiment - Shushtari Hospital
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Shiraz University of Medical Sciences

Full name of responsible person
Dr.Gholamreza Hatam

Street address
Research_seven floors_University of Central Building_
near red crescent_zand avenue_Shiraz

City
Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Shiraz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences, Division of Hematology, Oncology and Stem Cell Transplantatio

Full name of responsible person
Dr. Mani Ramzi

Position

Specialty in oncology, Associate
Other areas of specialty/work
Street address
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Person responsible for updating data

Contact

Name of organization / entity
Shiraz Univesity Of Medical Science

Full name of responsible person
Zahra Masoudi

Position
Student Master of Midwifery

Other areas of specialty/work

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Fatemeh (P.B.U.H) School Of Nursing & Midwifery,
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z.masoudi2007@yahoo.comz.masoudi85@gmail.com
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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