Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of doula supportive care and acupressure on the intensity of fetal hypoxia and frequency of nucleated red blood cells in the cord blood

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 on the intensity of fetal hypoxia and frequency of nucleated red blood cells in the cord blood. 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 correct and appropriate information which led to the mother's tranquility, understanding the origin of pain, developing a positive attitude toward the pain experience, and increase in their cooperation in the delivery progress. 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. The blood from the umbilical cord sent to laboratory and results record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081411706N3**
Registration date: **2013-08-23, 1392/06/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Zahra Masoudi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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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 of the effect of doula supportive care and acupressure on the intensity of fetal hypoxia and frequency of nucleated red blood cells in the cord blood

Public title

The effect of doula supportive care and acupressure on the intensity of fetal hypoxia and frequency of nucleated red blood cells in the cord blood

Purpose
Treatment
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; blood group 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
Fetal hypoxia
ICD-10 code
P20.1
ICD-10 code description
Intrauterine hypoxia first noted during labour and delivery

2

Description of health condition studied
Nucleated red blood cells in cord blood
ICD-10 code
R71
ICD-10 code description
Abnormality of red blood cells

Primary outcomes

1

Description
anxiety
Timepoint
Before and after intervention
Method of measurement
Spielberger questionnaire

2

Description
The number of nucleated red blood cells in cord blood
Timepoint
Smears of blood from the umbilical cord and peripheral blood under the microscope
Method of measurement
Blood tests

3

Description
fetal hypoxia
Timepoint
Smears of blood from the umbilical cord and peripheral blood under the microscope
Method of measurement
Cord blood red cell count of the peripheral smear

Secondary outcomes

empty

Intervention groups

1

Description
the researcher as the doula was beside the mother from her entrance into the department. She reassured the mother, encouraged her, and gave her correct and appropriate information which led to the mother's

tranquility, understanding the origin of pain, developing a positive attitude toward the pain experience, and increase in their cooperation in the delivery progress.

Category

Treatment - Other

2

Description

second intervention: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.

Category

Treatment - Other

3

Description

The third group: 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

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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

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Person responsible for updating data

Contact

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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, Namazi squear, Shiraz.

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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