

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation Of Neonatal Outcome Of Fetus Heart Monitoring With Intermittent Auscultation And Permanent Monitoring In Low Risk Women During Labor

Protocol summary

Summary

The purpose of this study is the assessment of the effect of permanent fetus heart monitoring among low risk pregnancies during labor. In this study, 900 pregnant women who have one cephalic fetus, being in labor phases and not having the exclusion criteria such as IUGR; diabetes; preeclampsia will randomly assigned to 2 intervention and control groups using sealed envelopes. In intervention group, the FHR will be assessed by sonicate every 15 minutes and in control group the FHR will be assessed through monitoring machine permanently. After labor, neonatal outcomes such as Apgar score and root of delivery will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102330437N2**

Registration date: **2017-02-16, 1395/11/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-16, 1395/11/28

Registrant information

Name

Lida Jedi

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3768 6199

Email address

jeddi1931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University Of Medical Science

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Of Neonatal Outcome Of Fetus Heart Monitoring With Intermittent Auscultation And Permanent Monitoring In Low Risk Women During Labor

Public title

Evaluation Of Neonatal Outcome Of Fetus Heart Monitoring

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria : Pregnant women with one cephalic fetus admitted for labor. Exclusion criteria : More than one fetus; Previous fetal death; Preeclampsia; Diabetes; Intra uterine growth retardation; Sepsis; Chorioamnionitis; Vaginal bleeding; Oxytocin usage.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 900

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done using sealed envelopes

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University Of Medical Science

Street address

Pardise University, Azadi Square

City

Mashhad

Postal code

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.MUMS.fm.REC.1395.163

Health conditions studied

1

Description of health condition studied

Neonatal Out Come In Low Risk Pregnancy

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Neonatal Apgar Score

Timepoint

One minute and 5 minutes after birth

Method of measurement

Apgar Score Scale

Secondary outcomes

1

Description

Delivery by Cesarean Section

Timepoint

After Neonate Birth

Method of measurement

Registration documents

2

Description

Asphyxia

Timepoint

After Neonate Birth

Method of measurement

Nochal cord PH, clinical examination

3

Description

NICU Admission

Timepoint

After Neonatal Birth

Method of measurement

Registration documents

Intervention groups

1

Description

Intervention Group 1:Permanent FHR monitoring during labor with Bionet Fetal Monitor Machine made in Korea

Category

Diagnosis

2

Description

Control Group:FHR control with Bionet sonicate made in Korea every 15 minutes during labor.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Lida Jedi

Street address

Taghi Abad Square

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Lida Jedi

Street address

Emam Reza Square

City

Mashhad

3

Recruitment center

Name of recruitment center

Omol-Banin Hospital

Full name of responsible person

Lida Jedi

Street address

16th Behjat Khorasani Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Pardis University, Azadi Square

City

Mashhad

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,Mashhad 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

Mashhad University Of Medical Science

Full name of responsible person

Lida Jedi

Position

Obstetrics And Gynecology Assistant

Other areas of specialty/work

Street address

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**Person responsible for scientific
inquiries**

Contact

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Full name of responsible person

Leila Pourali

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Lida Jedi

Position

Obstetrics and Gynecology Assistant

Other areas of specialty/work

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Ghaem Hospital
City
Mashhad
Postal code
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jeddil931@mums.ac.ir
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