Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effectiveness of implementation of evidence based clinical practices on mother and newborn outcomes during normal labor and delivery

Protocol summary

Summary

A single-blind, randomized controlled clinical trial will be conducted between May and September 2014 at Shahid Beheshti hospital, affiliated to Isfahan University of Medical Sciences, Isfahan, Iran. This study was approved by the ethics committee at the Isfahan University of Medical Sciences. The aim of this study is to compare the effect of «evidence based care» with «routine care » on mother and newborn outcomes during normal labor and delivery. Two hundred low risk pregnant women aged 18-35 years will be randomly allocated to receive either «evidence based care» or «routine care». One hundred were allocated to intervention group and 100 to control group. The main outcome of the study including duration of active phase and second stage of labor, labor Pain intensity, frequency use of oxytocin during normal labor, frequency use of routine episiotomy, postpartum hemorrhage, spontaneous tears in perinea and vagina, method of delivery, average time of admission to discharge, mother's satisfaction of delivery, newborns Apgar score, frequency newborns admission to neonatal ward or NICU, breast feeding during 30 minute after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050411360N1**
Registration date: **2014-05-11, 1393/02/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-11, 1393/02/21

Registrant information

Name

Mina Iravani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of implementation of evidence based clinical practices on mother and newborn outcomes during normal labor and delivery

Public title

Evidence Based Labor and Normal Delivery Management: A Mixed Methods Study

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: intend to participation in study; low risk pregnant women; maternal age 18-35 years old; single pregnancy; gestational age 38-42 weeks; vertex presentation; spontaneous labor pain; vaginal dilatation

between 3 and 4 centimeter; mother BMI 19.8-26 kg/m2; estimated fetal weight 2500-4000 gr. Exclusion criterion: unwillingness or reject of participation in study

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: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 the Isfahan University of Medical Sciences

Street address
Research Dupty of Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran.

City
Isfahan

Postal code
8174673461

Approval date
2012-08-12, 1391/05/22

Ethics committee reference number
391206

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
O80

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Duration of active phase and second stage of labor

Timepoint
Cervix dilatation from 4 centimeter to 10 centimeter for active phase of labor and cervix dilatation from 10 centimeter to delivery of newborn for second stage of labor

Method of measurement
Clinical examination/ Measurement by digital chronometer / record in check list

2

Description
Labor Pain intensity

Timepoint
Measurement severity of pain during first and second stage of labor

Method of measurement
By visual analog scale/ record in check list

3

Description
Frequency use of oxytocin during normal labor

Timepoint
During first and second stage of normal labor

Method of measurement
Observation / record in check list

4

Description
Frequency use of routine episiotomy

Timepoint
Before of delivery

Method of measurement
Observation and record in check list

5

Description
Post partum hemorrhage

Timepoint
After childbirth

Method of measurement
Measurement of HG and HCT level by blood sampling 12 and 24 h after childbirth

6

Description
Spontaneous tears in perinea and vagina

Timepoint
After of delivery

Method of measurement
Observation / clinical examination/ record in check list

7

Description
Method of delivery
Timepoint
After of delivery
Method of measurement
Observation and record in check list

8

Description
Mother’s satisfaction of delivery
Timepoint
Before discharging of hospital
Method of measurement
Macky satisfaction questionnaire

9

Description
Apgar score
Timepoint
1 and 5 minute after of delivery
Method of measurement
Observation and record in check list

10

Description
Frequency newborn admission to neonatal ward or NICU
Timepoint
After of delivery
Method of measurement
Observation and record in check list

11

Description
Breast feeding during 30 min after birth
Timepoint
during30 min after birth
Method of measurement
Observation and record in check list

12

Description
Average time of admission to discharge of mother
Timepoint
Of admission time to discharge
Method of measurement
Measurement by Digital chronometer / record in check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The subjects in this group will receive evidence based care during normal labor and delivery
Category
Other

2

Description
Control group: This group will be received routine care of hospital during normal labor and delivery
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Medical and Training Hospital of Isfahan University of Medical Sciences
Full name of responsible person
Mrs. Mina Iravani and Dr. Elahe Zarean
Street address
Beheshti Hospital of Isfahan University of Medical Sciences, Pol Felezi- Motaheri Street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr Peyman Adibi
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Grant name
فصل دوم برنامه تحقیقات دانشگاهی
Grant code / Reference number
10506-1191
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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, Nursing and Midwifery School

Full name of responsible person
Mina Iravani

Position
PhD candidate in Reproductive Health

Other areas of specialty/work

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Position
PhD candidate in Reproductive Health; Assistant Professor-Fellowship in Prinatology; Professor in Ep

Other areas of specialty/work

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Person responsible for updating data

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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