Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Design, Implementation and Evaluation of a plan for Labor and Normal Delivery Based on Evidence-Based Clinical Practice: A mixed methods evaluation design

Protocol summary

Study aim
Determining the effect of the implementation of a plan for Labor and Normal Delivery based on evidence-based clinical practice on maternal and newborn outcomes

Design
The study is a mixed method design with an evaluation plan (primary clinical trial study and qualitative study). The clinical trial has a control group, with a parallel group, randomized, on 256 primiparous women.

Settings and conduct
The research environment is the maternity hospital of Sina Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria Consent to participate in the study Primiparous women singleton pregnancy live fetus Mother's age is 15-49 years Gestation age 37 to 42 weeks Normal fetal heart rate Exit criteria History of any incision on the uterus Diagnosis of abnormal dimensions of the pelvis Abnormal bleeding Epidural anesthesia The presence of any abnormalities in the soft or bony tissue of the birth canal Having an abnormal fetus or intrauterine growth restriction Indication for caesarean section Known medical diseases based on the patient's file Fetal membranes that have been ruptured for more than 8 hours. high risk pregnancy

Intervention groups
In the intervention group of the Department of a plan for Labor and Normal Delivery , it will be performed by trained midwives based on the evidence-based designed program.

Main outcome variables
Labor and delivery management program based on evidence-based practices, satisfaction with delivery, experience of delivery, pain in the stages of delivery, length of delivery, type of delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181214041963N2**
Registration date: **2023-02-03, 1401/11/14**
Registration timing: **prospective**

Last update: **2023-02-03, 1401/11/14**
Update count: **0**

Registration date
2023-02-03, 1401/11/14

Registrant information

Name
Atefeh Ebrahimian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3420 0651

Email address
ebrahimiyan127@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Design, Implementation and Evaluation of a plan for Labor and Normal Delivery Based on Evidence-Based Clinical Practice: A mixed methods evaluation design

Public title
Design, Implementation and Evaluation of a plan for Labor and Normal Delivery

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study primiparous women singleton pregnancy live fetus maternal age 15-49 years gestational age 37 to 42 weeks (based on the first day of the last menstrual period or first trimester ultrasound) cephalic presentation normal fetal heart rate (110 -160)

Exclusion criteria:
history of any incision on the uterus - detection of abnormal dimensions of the pelvis through vaginal examination and examination of ischial spines, obstetric conjugation, sacrum concavity, condition of pelvic wall(s) and pubic arch angle abnormal bleeding epidural anesthesia presence of any abnormalities in soft tissue or Bony birth canal (diagnosed through vaginal examination) having an abnormal fetus or intrauterine growth restriction indication for cesarean section (fetal distress, prolapse of the umbilical cord, diagnosis of absolute pelvic stenosis by the doctor) known medical diseases based on the patient's file including history or current suffering from any systemic disease such as diabetes, high blood pressure, heart disease, kidney disease, nervous disease, liver disease, digestive disease, respiratory disease, thyroid disease) Fetal membranes that have been ruptured for more than 8 hours High-risk pregnancy (preeclampsia, placenta previa, Placental abruption, chorioamnionitis, placenta accreta)

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **256**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by the available method. In this way, since the beginning of the study, all mothers who meet the entry criteria and do not meet the exit criteria have been selected as samples, and this work will continue until the final sample size is reached. allocation to random groups: Research units will be assigned to intervention and control groups using random block method (six blocks). In this way, first 6 possible states of blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB) are listed and a number from one to six will be assigned to each block. Then a number between one and six is randomly selected using the random number table, and then people are selected based on the block corresponding to the number. will be assigned to the intervention (A) and control (B) groups. This work will continue until the sample volume is completed.

Blinding (investigator's opinion)
Single blinded

Blinding description
The statistical analyst is unaware of the type of intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan

City
Ahvaz

Province
Khouzestan

Postal code
37333-61349

Approval date
2023-01-28, 1401/11/08

Ethics committee reference number
IR.AJUMS.REC.1401.514

Health conditions studied

1

Description of health condition studied
Design, Implementation and Evaluation of a plan for Labor and Normal Delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Type of delivery

Timepoint
after the study

Method of measurement
Questionnaire

2

Description
Satisfaction with childbirth
Timepoint
after the study
Method of measurement
Mackey questionnaire

3

Description
Childbirth Experience
Timepoint
after the study
Method of measurement
Childbirth Experience Questionnaire

4

Description
The pain of childbirth
Timepoint
During the study
Method of measurement
Visual Analogue Scale

5

Description
The length of labor stages
Timepoint
During the study
Method of measurement
Check list

6

Description
Apgar first and fifth minutes
Timepoint
After the intervention
Method of measurement
check list

7

Description
Hospitalization in the neonatal intensive care unit
Timepoint
After the intervention
Method of measurement
check list

8

Description
Postpartum bleeding
Timepoint
During the study
Method of measurement
check list

9

Description
Genital lacerations
Timepoint
During the study
Method of measurement
check list

Secondary outcomes

1

Description
Early breastfeeding
Timepoint
During the study
Method of measurement
check list

Intervention groups

1

Description
Intervention group: In the intervention group of the Department of Labor and Natural Birth, it will be performed by trained midwives based on the evidence-based designed program.
Category
N/A

2

Description
Control group: In the control group, the Department of Labor and Natural Delivery will be performed according to the routine care of the hospital by providers other than trained people.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Ahvaz Hospital
Full name of responsible person
mina iravani
Street address
Golestan Boulevard
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Email

ebrahimiyan127@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Golestan Boulevard
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Ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
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Email
ebrahimiyan127@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
70
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
mina iravani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate professor
Latest degree
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
atefeh ebrahimian
Position
PhD student
Latest degree
Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The reviewed data can be shared without mentioning the names of people

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Policymakers, researchers in academic and scientific institutions

Under which criteria data/document could be used

If you have an official letter from the scientific center

From where data/document is obtainable

Request from the printed magazine and indexed sites, request via e-mail of the project manager

What processes are involved for a request to access data/document

6 months after completing the study of the application, the data will be sent to the project manager, if the conditions are met, up to two months.

Comments