Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness of management of labor and delivery with using training on evidence-based cares based on the world health organization safe childbirth checklist and routine performance on maternal and neonatal outcomes

Protocol summary

Study aim
Implementing and evaluation labor and delivery management program using the world health organization safe childbirth checklist

Design
This study will be Stratified randomized controlled trial across eligible governmental hospitals in Ahvaz. four eligible hospitals will be identified. We will match hospitals (i.e. strata) according being educational or not so that We will have an educational hospital and a non-educational hospital in each strata. Due to the fact that randomization will be performed on the basis of hospitals, not individually, the women admitted in each of these hospitals will be assigned to only one intervention group. Sampling of pregnant women will be done in convenience non -probability. All eligible women will select as a subject and this will be continued until we can gain the final sample size in each center.

Settings and conduct
Taleghani and Imam Khomeini are educational hospitals and Sina and Allameh Karami are not . In intervention groups pregnant women will be recieved evidence-based cares in accordance with the Safe Childbirth Checklist and control groups will be recieved routins care. Maternal and neonatal outcomes in each pregnant woman will be observed and recorded. Then ,they will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All providers who will be trained on evidence-based cares in accordance with the Safe Childbirth Checklist. singleton pregnant women with gestational age 37 weeks or over who are admitted for vaginal delivery

Intervention groups
all care providers in intervention hospitals will be trained Necessary training on evidence-based cares based on World Health Organization Safe Childbirth Checklist. Care providers in control hospitals will provide routine cares

Main outcome variables
Mother’s satisfaction of delivery , Mother’s experience of delivery and the type of delivery

General information

Reason for update
The type of sampling has been cluster randomized but it has the characteristics of stratified sampling and due to the low number of births in hospitals, it took six months instead of two months to reach the sample size.

Acronym

IRCT registration information
IRCT registration number: **IRCT20220501054711N1**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**
Update count: **1**

Registration date
2022-05-10, 1401/02/20

Registrant information

Name
Atefeh Kamrani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3328 1757

Email address
kamrani.a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-05, 1401/03/15
Expected recruitment end date
2022-09-06, 1401/06/15
Actual recruitment start date
2022-06-05, 1401/03/15
Actual recruitment end date
2022-12-06, 1401/09/15
Trial completion date
2023-01-20, 1401/10/30

Scientific title
Comparison of the Effectiveness of management of labor and delivery with using training on evidence-based cares based on the world health organization safe childbirth checklist and routine performance on maternal and neonatal outcomes

Public title
Implementing and evaluation labor and delivery management program using the world health organization safe childbirth checklist :An Embedded mixed-method study
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
All care providers who are responsible for caring for women who have been admitted for childbirth Pregnant women who have inclusion critria All Pregnant women who have singleton pregnancy and with gestational age 37 weeks or over with any ages, ethnicity, any history of obstetrics and any number of deliveries, who are admitted for vaginal delivery
Exclusion criteria:
Reluctance to participate in the trial
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **944**
Actual sample size reached: **944**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be a Stratified randomized controlled trial across eligible governmental hospitals in Ahvaz. four eligible hospitals will be identified. We will match hospitals (i.e.strata) according being educational or not, so that We will have an educational hospital and a non-educational hospital in each strata. Due to the fact that randomization will be performed on the basis of hospitals, not individually, the women admitted in each of these hospitals will be assigned to only one intervention group. 236 eligible pregnant women will be enrolled in each of the hospitals and this will be continued until we can gain the final sample size in each center. Sampling of pregnant women will be done in convenience non -probability.
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 committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ethics committee of Ahvaz Jundishapur University of Medical Sciences, Farvardin street, Gorleston Blvd
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2022-04-16, 1401/01/27
Ethics committee reference number
IR.AJUMS.REC.1401.049

Health conditions studied

1

Description of health condition studied
Normal vaginal Delivery Management
ICD-10 code
O80
ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Mother’s satisfaction of delivery
Timepoint
Before discharging of hospital
Method of measurement
Mackey Childbirth Satisfaction Rating Scale

2

Description
Mother’s experience of delivery
Timepoint
4-6 weeks after delivery
Method of measurement
childbirth experience questionnaire 2/0

3

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

Secondary outcomes

1

Description
Apgar score below 7
Timepoint
At 1 and 5 minutes after birth
Method of measurement
Observation and examination

2

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

3

Description
Shoulder dystocia
Timepoint
During delivery
Method of measurement
Observation and record in check list

4

Description
Postpartum hemorrhage
Timepoint
after of delivery
Method of measurement
Increased maternal pulse rate above 110 beats per minute and maternal systolic blood pressure less than 90 mm Hg with vaginal bleeding. Hematocrit will be measured at baseline and then 8 hours after delivery.

5

Description
Maternal infections
Timepoint
During labor and delivery up to 42 days after delivery
Method of measurement
Sublingual temperature of 39 degrees or more or between 38-39 degrees that persists after 30 minutes Examination/ record in check list

6

Description
Frequency of third and fourth-degree perineal lacerations
Timepoint
After of delivery
Method of measurement
Observation and record in check list

7

Description
Near miss morbidity
Timepoint
From the time of hospitalization until 42 days after delivery
Method of measurement
Based on cardiovascular, pulmonary, renal, hepatic and uterine dysfunction

Intervention groups

1

Description
Intervention group: In intervention groups, the Labor and delivery program management will be based on evidence-based care in accordance with the World Health Organization safe childbirth checklist. In these hospitals, the researcher will give the necessary training of labor and delivery management program based on evidence-based care standards in according to the safe childbirth checklist to all care providers (midwives, residents, gynecologists) who work in labor and delivery ,the operating room and postpartum ward. These trainings will be done in groups of ten over several three-hour sessions, so that all care providers will be able to participate in these sessions. Training will be in the form of lectures, training booklets and practical simulations. After training in the intervention hospitals, volunteer care providers to participate in the trial, will manage labor and delivery according to the mentioned program . In order to reduce the probability of error in the study, the people evaluating the maternal and neonatal consequences will be different from the people in the research group. Four evaluators (midwives with 5 to 7 years of Work experience) will receive the necessary training by the researcher during two, two-hour training sessions on how to assess maternal and neonatal outcomes. To reduce the error of bias by the evaluators, they do not have any employment cooperation in the mentioned hospitals. Initially, according to the data quality assurance protocol, the researcher will evaluate the maternal and neonatal outcomes with the evaluators

until each evaluator achieves 100% accuracy and compliance with the standard in the evaluation of maternal and neonatal outcomes. Then they will follow up maternal and neonatal outcomes independently in intervention and control hospitals. Neonatal outcomes up to 7 days and maternal outcomes up to 42 days after delivery will be followed up and compared in both groups.

Category

N/A

2

Description

Control group: current position

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital karoon

Full name of responsible person

Atefeh Kamrani

Street address

Sina hospital, 5th Gandomkar Ave, Imam Ali Square, Kut Abdullah

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2

Recruitment center

Name of recruitment center

Imam khomeiney hospital

Full name of responsible person

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Imam khomeiney hospital, Azadegan Blvd

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3

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Atefeh Kamrani

Street address

Taleghani hospital, phase2 Padashahr

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4

Recruitment center

Name of recruitment center

Allameh Karami hospital

Full name of responsible person

Atefeh Kamrani

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Email

info@karamihospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerzadeh

Street address

School of Nursing and Midwifery, Jundishapur University of Medical Sciences, University town

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Email

itc@ajums.ac.ir

Web page address

http://vchresearch.ajums.ac.ir

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

100

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

Atefeh Kamrani

Position

Phd of midwifery student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mina Iravani

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Associate professor

Latest degree

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Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Name of organization / entity

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Position

Ph.D of Midwifery student

Latest degree

Master

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Jundishapur University of Medical Sciences, Farvardin street, Golestan Blvd

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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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

The data of this study will be accessible upon the request form the corresponding author after publication, or we may deposit our data in the “Figshare” for sharing with other researchers after the publication of the manuscript.

When the data will become available and for how long

The data will be accessible upon the request from the corresponding author or in the Figshare” after publication of the manuscript (we anticipate this time by the end of 2023).

To whom data/document is available

Our data will be accessible upon the request from faculty members who interested to use our data with the research purpose (with acknowledgement of authors in our study)

Under which criteria data/document could be used

Interested researchers can send an e-mail to the corresponding author and request our data. In case of if we deposited our data in the “Figshare” cite, they will be accessible from the cite

From where data/document is obtainable

Mina Iravani-Iran, Ahvaz, Golestan Ave, Ahvaz Jundishapur University of Medical Sciences, Nursing & Midwifery School, Midwifery Department

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

The requested information will be sent at the most up to one week after receiving the email

Comments