# 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)

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+98 86 3328 1757

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**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**

Atefeh Kamrani

**Street address**

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himam@ajums.ac.ir

**Web page address**

http://bankpezeshkan.co

**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

**Street address**

Allameh Karami hospital, Baharan street

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Zakerzadeh

**Street address**

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**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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Jundishapur medical university, Farvardin street, Gorleston Blvd

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Associate professor

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Position**

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**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**

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**