

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of maternal and neonatal outcomes in caring by Doula, trained lay companion and routine midwifery care : A Quasi-Experimental Study

#### Protocol summary

##### Study aim

Comparison of maternal and neonatal outcomes in caring by Doula, trained lay companion and routine midwifery care

##### Design

A quasi-experimental study with an control group and two interventional group, Randomized and not being blinded, Phase3 on150 pregnant

##### Settings and conduct

In the control group and the trained companion, the samples were taken from 10 clinics of different parts of the Arak city by random sampling method using the SIB center system. Then, among selected numbers, we randomly selected samples for each group. But in Doula group, because of limited number of samples, convenience sampling was used and all women enrolled in doula care were included in the study until the number reached 50

##### Participants/Inclusion and exclusion criteria

The criteria for entering: Low-risk pregnant women aged 18 to 40 years, Gestational age of 38 to 42 weeks, Spontaneous onset of labor pains, And Healthy, Live, Single fetus with display of head and normal cervical delivery conditions. The criteria for not enterain: Any physical and Mental disease

##### Intervention groups

For the samples of the trained companion group, Two training sessions were given in the presence of mothers and their selected companion on the course of labor and techniques to reduce labor pain, skin-to-skin contact and breastfeeding. People in the care group were selected by doulas from private midwifery centers that were available. In these centers, a doula is considered for all mothers and during labor, mothers are trained according to their routine. The samples of the control group were taken care by the usual routine of medical training centers.

#### Main outcome variables

The duration of the active phase and second stage of labor, Satisfaction with childbirth, Anxiety during labor, Pain intensity, Time to start and duration of skin-to-skin contact, Time to start and duration of breastfeeding, Apgar first and fifth minutes of birth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230620058548N1**

Registration date: **2023-08-29, 1402/06/07**

Registration timing: **retrospective**

Last update: **2023-08-29, 1402/06/07**

Update count: **0**

##### Registration date

2023-08-29, 1402/06/07

##### Registrant information

##### Name

afsaneh azadpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3366 6593

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-21, 1397/04/30

##### Expected recruitment end date

2019-06-10, 1398/03/20  
**Actual recruitment start date**  
2018-07-21, 1397/04/30  
**Actual recruitment end date**  
2019-06-10, 1398/03/20  
**Trial completion date**  
2019-06-10, 1398/03/20

**Scientific title**

Comparison of maternal and neonatal outcomes in caring by Doula, trained lay companion and routine midwifery care : A Quasi-Experimental Study

**Public title**

Comparison of maternal and neonatal outcomes in caring by Doula, trained lay companion and routine midwifery care

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Low-risk pregnant women aged 18 to 40 years  
Gestational age of 38 to 42 weeks based on accurate LMP or ultrasound  
Spontaneous onset of labor pains  
Healthy, live fetus  
Single fetus  
Display of head Normal cervical delivery conditions according to midwife or physician

**Exclusion criteria:**

Any known physical disease related or unrelated to pregnancy  
Mental illness of mother  
Known fetal abnormalities  
Previous history of cesarean section or desire to have selective cesarean section  
History of giving birth to infant who weighs less than 2500 or more than 4000 grams

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

Actual sample size reached: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the accompanying group trained to select samples, we entered the SIB system in 10 selected health centers in Arak city and extracted the list of pregnant mothers who met the criteria for entering the study, and then the mothers were asked to enter the study and those who agreed were randomly selected. became A simple random sampling method was used to select the mothers of these centers. We had a list of all the mothers of this center (from 1 to 389), then using Excel, a number was randomly generated for each mother, and the required 50 samples (from number 1 to 50) were taken. The group of doulas were selected from midwife counseling centers and compassionate midwives using available sampling method. 62 mothers who registered

for doula from July 2017 to June 2018 were selected from Taleghani, Sina and Imam Khomeini (RA) hospitals. A simple random sampling method was used to select the mothers of this group as well as the companion group. After presenting a list of all the mothers of this center (from 1 to 62), we randomly generated a number for each mother using Excel. This study was initially designed as a randomized trial, but when we reached the sampling stage, we realized that due to the small number of centers and the small number of mothers who want to receive support from midwives, it is not possible to randomly allocate the samples in groups. Differently, the study was conducted in a semi-experimental manner, so that only random sampling was done. But the allocation of samples to groups was not done randomly. The samples of the control group were mothers who referred to Taleghani Hospital for prenatal care. From September 1397 to Mehr 1397, like the Dola group and the companion group, we used simple random sampling to select the mothers of the control group, based on which a list of all the mothers of this hospital who met our criteria (from 1 to 95) was presented, then we A number was randomly generated for each mother using Excel and 50 samples (numbers 1 to 50) were taken from 95 mothers.

**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 Tehran University of Medical Sciences

**Street address**

Central Building of Tehran University of Medical Sciences, Intersection of Qods Street, Keshavarz Boulevard, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2018-09-01, 1397/06/10

**Ethics committee reference number**

IR.TUMS.FNM.REC.1397.097

## Health conditions studied

1

### Description of health condition studied

Active phase duration

**ICD-10 code**

**ICD-10 code description**

2

### Description of health condition studied

Second stage duration

**ICD-10 code**

**ICD-10 code description**

3

### Description of health condition studied

Satisfaction with childbirth

**ICD-10 code**

**ICD-10 code description**

4

### Description of health condition studied

Anxiety during labor

**ICD-10 code**

**ICD-10 code description**

5

### Description of health condition studied

Duration of skin-to-skin contact

**ICD-10 code**

**ICD-10 code description**

6

### Description of health condition studied

Severity of labor pain

**ICD-10 code**

**ICD-10 code description**

7

### Description of health condition studied

Time to start breastfeeding

**ICD-10 code**

**ICD-10 code description**

8

### Description of health condition studied

Apgar score in the first and fifth minutes of birth

**ICD-10 code**

**ICD-10 code description**

9

### Description of health condition studied

Time to start skin-to-skin contact

**ICD-10 code**

## ICD-10 code description

10

### Description of health condition studied

Duration of skin-to-skin contact

**ICD-10 code**

**ICD-10 code description**

11

### Description of health condition studied

How to contact mother and infant

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

### Description

Active phase duration of labor

### Timepoint

Dilatation of 3-10 cm

### Method of measurement

Researcher-made checklist

2

### Description

Second stage duration of labor

### Timepoint

From 10 cm dilatation to complete exit of placenta

### Method of measurement

Researcher-made checklist

3

### Description

Satisfaction birth

### Timepoint

24 hours after delivery

### Method of measurement

Satisfaction birth questionnaire by Hollins Martin

4

### Description

Anxiety of mothers during labor

### Timepoint

From 3 to 10 cm dilatation and then 8-10 cm

### Method of measurement

The Spielberger covert and overt anxiety questionnaire

5

### Description

Duration of skin-to-skin contact

### Timepoint

Postpartum

### Method of measurement

Researcher-made checklist

## 6

### **Description**

Severity of pain

### **Timepoint**

At the time of admission, the first, second, third, fourth and fifth hour after admission

### **Method of measurement**

Visual Analogue Scale for pain

## 7

### **Description**

Duration of skin-to-skin contact

### **Timepoint**

postpartum

### **Method of measurement**

Researcher-made checklist

## 8

### **Description**

How to contact mother and infant

### **Timepoint**

Postpartum

### **Method of measurement**

Researcher-made checklist

## 9

### **Description**

Time to start skin-to-skin contact

### **Timepoint**

Postpartum

### **Method of measurement**

Researcher-made checklist

## 10

### **Description**

Time to start feeding

### **Timepoint**

Postpartum

### **Method of measurement**

Researcher-made checklist

## 11

### **Description**

Apgar first and fifth minutes after birth

### **Timepoint**

Postpartum

### **Method of measurement**

Birth information

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: Care by doula: The samples of the care group were selected by accompanying midwives from private midwifery service centers. The accompanying midwife was also one of the staff of the center who personally undertakes all care services within the scope of duties of the accompanying midwife in labor, but the delivery was performed by the ward personnel. Accompanying midwife, while being with the mother and providing continuous midwifery care, evaluating the progress of childbirth, examining the health status of the mother and fetus in order to maintain the physiological process of childbirth and avoid any unnecessary intervention by providing emotional support, training to control fear and worry and training how to control Pain helped to increase the mother's peace and comfort. The support provided to the mother during the stages of labor by the midwife are: constant presence at the mother's bedside, reassurance, establishing a close relationship, listening to the mother's concerns and words, encouraging proper breathing techniques, using massage or compresses. cold or local heat (according to the mother's desire), training to relax the body with visualization, giving simple and understandable information about the stages of childbirth, encouraging frequent emptying of the bladder, helping and encouraging mobility and changing the position, keeping the mother informed From the progress and process of childbirth by performing vaginal examinations and controlling contractions, helping the mother to be in a comfortable position, encouraging the mother to deliver early when necessary, strengthening the morale, preparing the mother for childbirth, advising the mother to cooperate with the birth attendant and Teaching the correct way to breathe and apply pressure when trying to expel the fetus, giving information about the importance of skin-to-skin contact with the baby immediately after delivery and early breastfeeding and the need for the mother's cooperation. After delivery, the mother was supported to communicate with the baby through skin-to-skin contact and early breastfeeding.

### **Category**

N/A

## 2

### **Description**

Intervention group: Care by trained lay companion: inThe trained (lay) companion group The mothers were asked to nominate a person of their choice to accompany them during the labor and birth. A trained person should have at least one experience of childbirth. After being selected by the mother and introduced to the research team, they were invited to participate in educational classes, during which they were taught how to care for the mothers during labor. They were also assured that they would be notified of the time of the classes. After sampling was completed in this group, two training sessions were designed and the time of these sessions was coordinated with the mothers and their companions. Since a number of samples were excluded from the study for reasons such as not attending the training sessions, same number of eligible people were randomly assigned to the study to prevent any problem in statistical analysis. The

mothers of this group finally gave birth in Imam Khomeini and Taleghani hospitals, according to their choice (Sina Hospital is private and Imam Khomeini and Taleghani Hospitals are public). In the sessions, topics such as stages of labor, symptoms of labor, measures needed to facilitate labor, and role of the companion before coming to the hospital including: helping a pregnant woman to go to the hospital if she sees any signs of labor, continuous presence beside the patient, gaining the trust, building a sincere relationship, listening to the mother's concerns and worries, encouraging proper breathing techniques, using massage or applying cold or hot compresses (according to the mother's wishes), teaching relaxation methods, giving simple and understandable information about the birth process, encouraging frequent emptying of the bladder, helping and encouraging mobility, changing the position during the labor and using the delivery ball if possible, keeping the mother informed of the progress and birth process, helping the mother to get comfortable, encouraging the mother to push when needed, boosting her mood, preparing the mother for childbirth, advising the mother to work with the birth agent and teaching her how to breathe properly, applying pressure when infant is coming out, giving information about the importance of skin-to-skin contact with the baby immediately after the birth and the importance of early breastfeeding, were taught. At the last session, the mothers and their companions were asked to inform the researcher when they see signs of childbirth, so that coordination could be made with the delivery and obstetric unit of Imam Khomeini and Taleghani Hospitals to accept them

#### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Taleghani Hospital

###### **Full name of responsible person**

Afsaneh Azadpour

###### **Street address**

Taleghani Educational Medical Center, Next to Gas Company, West side of Imam Khomeini Street, Arak

###### **City**

Arak

###### **Province**

Markazi

###### **Postal code**

3816149369

###### **Phone**

+98 86 3277 6034

###### **Email**

lt-taleghani@arakmu.ac.ir

###### **Web page address**

<http://arakmu.ac.ir/fa>

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Imam Khomeini Hospital

###### **Full name of responsible person**

Afsaneh Azadpour

###### **Street address**

Imam Khomeini hospital, Behind the southern ring road, Above Razavi settlement (Walnut), Ring road, Arak

###### **City**

Arak

###### **Province**

Markazi

###### **Postal code**

1457965595

###### **Phone**

+98 86 3278 2021

###### **Fax**

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###### **Email**

info@tamin.ir

###### **Web page address**

<https://emamkhomeini.tamin.ir>

#### **3**

##### **Recruitment center**

###### **Name of recruitment center**

Private midwifery center named Madaryar

###### **Full name of responsible person**

Afsaneh Azadpour

###### **Street address**

Unit 1, Ammar Alley, Shahid Beheshti Street, Arak

###### **City**

Arak

###### **Province**

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###### **Postal code**

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###### **Phone**

+98 86 3224 2558

###### **Email**

Afsaneh.azadpour@yahoo.com

#### **4**

##### **Recruitment center**

###### **Name of recruitment center**

Private midwifery center of the Mamaye mehrban

###### **Full name of responsible person**

Afsaneh Azadpour

###### **Street address**

Professor hesabi building, 17 metri intersection, Dr. Hasabi intersection, Arak

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###### **Province**

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###### **Phone**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Shahrzad Pashaeipour

**Street address**

Tehran University of Medical Sciences Headquarters,  
Qods Corner, Keshavarz Blvd.

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**Postal code**

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**Fax**

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**Email**

tumspr@tums.ac.ir

**Web page address**

<https://tums.ac.ir/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Afsaneh Azadpour

**Position**

Midwife

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

#### Street address

Bahar 3 Alley, Erfan Aven, Hepco Aven, Arak

#### City

Arak

#### Province

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#### Postal code

3818835543

#### Phone

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#### Email

Afsaneh.azadpour@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Afsaneh Azadpour

**Position**

Midwife

**Latest degree**

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**Other areas of specialty/work**

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#### Province

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Afsaneh Azadpour

**Position**

Midwife

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

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Arak

#### Province

Markazi

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

because of confidentiality the participants characteristics wont be shared.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available