Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 pregnants

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

afsaneh.azadpour@yahoo.com

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
It-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
+98 86 3278 4139

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
Markazi

Postal code
3813746153

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

City
Arak

Province
Markazi

Postal code
3813653562

Phone

+98 918 367 4358

Email
afsaneh.azadpour@yahoo.com

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.

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 81631

Fax
+98 21 8163 3125

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
Markazi

Postal code
3818835543

Phone
+98 86 3366 6593

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
Master

Other areas of specialty/work
Midwifery

Street address
Bahar 3 Alley, Erfan Aven, Hepco Aven, Arak

City
Arak

Province
Markazi

Postal code
3818835543

Phone
+98 86 3366 6593

Email
Afsaneh.azadpour@yahoo.com

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
Bahar 3 Alley, Erfan Aven, Hepco Aven, Arak

City
Arak

Province
Markazi

Postal code
3818835543

Phone

+98 86 3366 6593

Email

Afsaneh.azadpour@yahoo.com

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