

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

: Evaluation of continuous support by doula midwife during labor on duration, pain, and mode of labor in primiparous women

Protocol summary

decrease labor pain severity and duration and decrease cesarian delivery

Study aim

Evaluation of continuous support by doula midwife during labor on duration, pain, and mode of labor in primiparous women

Design

a double-blind clinical trial with a parallel-group design of 110 samples. The card drawing technique was used to randomize the assignment of subjects to the groups.

Settings and conduct

110 primiparous women referred to Imam Ali Amol hospital after obtaining the written consent of the qualified individuals, they will be placed in two groups with the support of a doula midwife and the control group (routine care) by a simple randomization method. In the doula support group, the doula midwives explain the delivery process and its progress for mothers by close physical and eye contact with them, assured them and made them calm, led them, and emphasized the relaxation. The control group received the care from midwifery personnel, two groups received the same general care during delivery (fetal heart rate control, vaginal examinations, maternal vital signs, etc.). To blind patients in two groups, the intervention and control groups will be admitted to separate rooms and vaginal examinations, labor progress, measurement of the pain severity was done by a researcher who was unaware of how groups were assigned.

Participants/Inclusion and exclusion criteria

The inclusion criteria included the primiparous women, live , term and singleton fetus, cephalic presentation the exclusion criteria: pregnancy disorders, the possibility of CPD, Caesarean indication.

Intervention groups

The control group received the care from midwifery personnel doula support group, the doula midwives visited patients from the moment of admission and accompanied mothers at all stages of labor and delivery and beside Providing routine care

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140924019277N2**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **retrospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Sussan Saatsaz

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 4422 1919

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-09-14, 1398/06/23

Trial completion date

2019-09-14, 1398/06/23

Scientific title

: Evaluation of continuous support by doula midwife during labor on duration, pain, and mode of labor in primiparous women

Public title

Evaluation of continuous support by dula midwife on labor process

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

all primiparous women with term , live and singleton fetus cephalic presentation and estimated fetal weight of 2500-3400 g,

Exclusion criteria:

patients with any chronic or mental illness, pregnancy disorders, the possibility of the narrow pelvis, a history of any kind of scar on the uterus, abnormal bleeding, fetal anomalies, fetal distress, and any kind of clear Caesarean induction. , the applicant or recipient of spinal or epidural anesthesia, withdraw from the study at any time

AgeFrom **20 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **110**Actual sample size reached: **105****Randomization (investigator's opinion)**

Randomized

Randomization description

The card drawing technique was used to randomize the assignment of subjects to the groups. A total of 110 identical cards were first prepared, and 55 were labeled A (routine care), 55 B(the private midwife support). A card was randomly drawn for each participant who entered the study by an independent assistant researcher (engaged only in the randomization process) and the type of intervention written on the card was announced by another researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the randomization process, the intervention and control groups were admitted to separate rooms. In addition to routine care by midwifery personnel, each patient in the intervention group will be cared for by doula midwife until the end of labor. For both groups, the results of the vaginal examination and the severity of the pain will be evaluated and recorded by a researcher who

is unaware of how the groups are allocated.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University Of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Valie-Asr Boulevard, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2017-12-23, 1396/10/02

Ethics committee reference number

IR.MAZUMS.REC.1396.2713

Health conditions studied**1****Description of health condition studied**

labor care Method

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain severity

Timepoint

every 3 hour

Method of measurement

Visual analog pain scale

2**Description**

labor duration

Timepoint

from the moment of admission [active phase beginning 2-3 hours and for the second and third stages separately from the beginning to the end of each stage

Method of measurement

vaginal exam and record

3

Description

delivery method

Timepoint

in the end of delivery

Method of measurement

observatio

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: continuous support by doula midwife during labor and delivery .doula midwife explained the delivery process and its progress for mothers by a close physical and eye contact with them, assured them and made them calm, led them and emphasized the relaxation, and put hot or cold bag on their back, belly or other body areas and applied massage upon the request.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Medical-Educational Center

Full name of responsible person

Sussan Saatsaz

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No .4 Shahrzad Ave Glayol 4.Tehran street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeidi

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Moalem Square , Parastar Street

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Sari

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Sussan Saatsaz

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity

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

Undecided - It is not yet known if there will be 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

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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Sussan Saatsaz

Position

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Other areas of specialty/work

Midwifery