Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
decrease labor pain severity and duration and decrease cesarian delivery

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

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Iran (Islamic Republic of)

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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

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target 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 houre 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
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Full name of responsible person
Dr Majid Saeidi
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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
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Person responsible for updating data

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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