

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### A comparative study on the effect of presence trained attendant and midwifery student in labor on some maternal and neonatal outcomes in nulliparous women

#### Protocol summary

##### Study aim

Comparison of mean pain score in the second stage of labor in intervention and control groups  
Comparison of mean anxiety score in intervention and control groups  
Comparison of Childbirth Satisfaction in intervention and control groups

##### Design

This is Randomizes Clinical Trial (RCT) study with a minimization method based on age and education and has two intervention and one control group and they are parallel. The sample size consists of 90 people and no medicine is used.

##### Settings and conduct

In this RCT study; The statistical population consists of pregnant women who referring to pregnancy classes. The sample size was estimated based on the statistical formula and calculated 30 people in each group (90 people total). The sampling method is randomization and the allocation will be done with the minimization method. The first intervention group is the last year midwifery students and the second intervention is a member of the pregnant mother's family and this study also has a control group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Willingness to to NVD Delivery at Niknafs Maternity Center of Rafsanjan Singleton pregnancy Age: 18 to 35 years  
Exclusion Criteria: The presence of medical disease Absolute contraindications of workout

##### Intervention groups

The first intervention group is a last-year midwifery student and the second intervention group is a member of the pregnant mother's family. Two intervention groups participate in pregnancy classes as mother's companions and will be in the pain room during childbirth to reduce delivery pain. The control group includes only mothers (as participants) and will be alone in pregnancy classes

and pain room without any companion.

##### Main outcome variables

The mean pain and anxiety score in the first stage of labor and the mean childbirth satisfaction score after delivery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190717044248N2**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

##### Registration date

2020-06-29, 1399/04/09

##### Registrant information

##### Name

Zahra Saghafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

z.saghafi@rums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-08-15, 1399/05/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study on the effect of presence trained attendant and midwifery student in labor on some maternal and neonatal outcomes in nulliparous women

**Public title**

A comparative study on the effect of presence trained attendant and midwifery student in labor on some maternal and neonatal outcomes

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study Willingness to to Normal Vaginal Delivery (NVD) Delivery at Niknafs Maternity Center of Rafsanjan Mother age: 18-35 years Gestational age: 20 weeks or more than it based on reliable first-trimester ultrasound or last menstrual period Singleton pregnancy

**Exclusion criteria:**

The presence of medical disease Absolute contraindications of workout History of psychological problems during 6 month ago Consumption of Antidepressant medication Drug consumption

**Age**From **18 years** old to **35 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will use convenience sampling. Among people referring to pregnancy classes, everybody who has inclusion criteria allocate with a minimization method based on age and education of variables. For each group, the first sample enters the study by the lottery method (Flip a coin). For the next samples, we consider the total number of the samples in every three groups and assign the sample to a group that has a lower number of members, and if the total number of samples in these groups becomes equal again, we will use the lottery method.

**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 Rafsanjan University of Medical Sciences

**Street address**

Emam Ali Blvd, Organization Center of Rafsanjan University of Medical Sciences, Rafsanjan, Iran.

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2018-12-12, 1397/09/21

**Ethics committee reference number**

IR.RUMS.REC.1397.157

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

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**2****Description of health condition studied**

Pain

**ICD-10 code**

F45.4

**ICD-10 code description**

Pain disorders related to psychological factors

**Primary outcomes****1****Description**

The mean time of first labor stage

**Timepoint**

From the active phase of labor to the second stage of it.

**Method of measurement**

Childbirth checklist

**Secondary outcomes**

## 1

### Description

Mean of pain score

### Timepoint

The active phase of labor (from 4 cm dilation to full dilation of cervix)

### Method of measurement

Checklist

## Intervention groups

## 1

### Description

The first intervention group is a last-year midwifery student that participates in pregnancy classes as mother's companions and will be in the pain room during childbirth to reduce delivery pain.

### Category

Prevention

## 2

### Description

The second intervention group is a member of the pregnant mother's family that participates in pregnancy classes as mother's companions and will be in the pain room during childbirth to reduce delivery pain.

### Category

Prevention

## 3

### Description

The control group includes only mothers (as participants) and will be alone in pregnancy classes and pain room without any companion.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Niknafs Maternity Center of Rafsanjan

#### Full name of responsible person

Asmat Javadi

#### Street address

No. 4, 7th Alley, South Panzdah-e-Khordad Ave

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7716765965

#### Phone

+98 34 3425 9030

#### Email

449@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Dr Ali Shamsizadeh

#### Street address

Emam Ali Street

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718146890

#### Phone

+98 34 3428 0072

#### Email

vcrt@rums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Azam Sharifi

#### Position

Obstetrician

#### Latest degree

Bachelor

#### Other areas of specialty/work

Midwifery

#### Street address

Saeb-e-Tabrizi Alley, Mohamadreza Dashti Ave, Dashti Blvd

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Rafsanjan

#### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
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Zahra Saghafi  
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Totur  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery  
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Nursing and Midwifery School, Sahely Blvd, Motahari Ave  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**

Zahra Saghafi  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
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**Street address**  
Nursing and Midwifery School, Sahely Blvd, Motahari Ave  
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7718796755  
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Saghafiz@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

Participants' information will remain confidential.

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable