

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of the presence of private midwife on anxiety and fear of giving birth in Pregnant Women referring to Hakim hospital in Neyshabour city

Protocol summary

Study aim

The purpose of the study was to determine the effect of the presence of a private midwife in comparison with the absence of a private midwife during labor on anxiety and fear of delivery of pregnant mothers.

Design

This is a randomized, clinical trial study, witnessed, on 80 pregnant women. Referred to the Hakim Hospital in Neyshabur for natural childbirth. At first, the patients will be assessed in terms of inclusion criteria and exclusion criteria. Then eligible patients will be selected by available sampling method. And patients were randomly divided into two control and intervention groups.

Settings and conduct

This is a randomized, clinical trial study, witnessed, on 80 pregnant women. Referred to the Hakim Hospital in Neyshabur for natural childbirth.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 18 to 35 years; hospitalization at the beginning of the active phase in maternity hospital; single embryo; fit the head of the fetus with the mother's hip; participation in childbirth preparation classes. Exclusion criteria: Physical and mental disease; the occurrence of any complications of pregnancy such as pre eclampsia; bleeding; diabetes; intrauterine fetal death; and tearing of an amniotic fluid bag during hospitalization.

Intervention groups

The test group is supported by a private midwife (who has completed a physiological delivery course for 60 hours) from the beginning of admission to two hours after delivery, will receive all midwifery services. But control group will only receive routine care from the non-private midwife.

Main outcome variables

The amount of anxiety and fear of delivery in the two groups, by Hamilton's Anxiety Inventory and Hartmann's

Maternity Distress Questionnaire, will be completed by the researcher, first before the intervention at 35th week of gestation and the second time of admission to labor and the third time in recovery by the researcher.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170921036302N3**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **retrospective**

Last update: **2018-01-05, 1396/10/15**

Update count: **0**

Registration date

2018-01-05, 1396/10/15

Registrant information

Name

sadigheh Khalili Shomia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8328

Email address

khalilis@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-05-30, 1396/03/09

Expected recruitment end date

2017-12-30, 1396/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the presence of private midwife on anxiety and fear of giving birth in Pregnant Women referring to Hakim hospital in Neishabour city

Public title

The Impact of Private Midwife on Anxiety and Fear of giving birth in Pregnant Women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 18 to 35 years Hospitalization at the beginning of the active phase in maternity hospital
Single embryo Fit the head of the fetus with the mother's hip Participation in childbirth preparation classes

Exclusion criteria:

Physical and mental disease Bleeding The occurrence of any complications of pregnancy such as preeclampsia Diabetes Intrauterine fetal death Tearing of an amniotic fluid bag during hospitalization

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **0**

Randomization (investigator's opinion)

N/A

Randomization description**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 Sabzevar University of Medical Sciences

Street address

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

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Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

ir.medsab.rec.1395.11

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

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2**Description of health condition studied**

Fear of giving birth

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety]

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

Anxiety in Pre-natal Patients

Timepoint

The first time before the intervention (35th week of pregnancy) and the second time of admission in the maternity hospital and the third time in the recovery room.

Method of measurement

Hamilton's Anxiety Inventory

2**Description**

Fear of giving birth

Timepoint

The first time before the intervention (35th week of pregnancy) and the second time of admission in the maternity hospital and the third time in the recovery room.

Method of measurement

Hartmann's fear of delivery

Secondary outcomes

empty

Intervention groups

1

Description

The test group is supported by a private midwife (who has completed a physiological delivery course for 60 hours) from the beginning of admission to two hours after delivery, will receive all midwifery services.

Category

Prevention

2

Description

Control group: Control group will only receive routine care from the non-private midwife.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Hospital in Neyshabur

Full name of responsible person

Masoumeh Omidvar

Street address

Hakim Neishabour Hospital, Baghrood Square, Basij Square, Neyshabur, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Fereshteh Gharat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Sadigheh Khalili Shomia

Position

Master of Science in Nursing Education, Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address**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**

Sabzevar University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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