Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

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

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)

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+98 51 4401 8328

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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
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: **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
City
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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omidvarm123@gjmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Doctor Fereshteh Gharat
Street address
Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi
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Email
SHOMIA@YMAIL.COM
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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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