Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of continuity of midwifery care during labor on child birth Outcomes in patients referring to 29 Bahman hospital, Tabriz, 1388.

Protocol summary

Summary

This study with quasi – experimental design, will be conducted to assess the effect of continuity of midwifery care, in childbirth course, on mother and child health, in non- complicated (medical and obstetrical complications in pregnancy) parturient, which referring to study center for normal vaginal delivery. Parturient in two groups, will receive different kind of midwifery care. In conventional care group: the clients will be cared (from admission time in delivery part till one hour after delivery) by a group of duty midwives, and visit regularly at 1:30–2 hour intervals, in admission and labor and delivery sections. But in continuity of care group, one midwife will care, from admission time in delivery part till one hour after delivery; she lefts clients bedside only for several minutes. Then consequences of each kind of care, as childbirth outcome, will be recorded in self administer check list and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104103027N4**
Registration date: **2011-07-11, 1390/04/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-11, 1390/04/20

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

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sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of the Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2009-06-22, 1388/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continuity of midwifery care during labor on child birth Outcomes in patients referring to 29 Bahman hospital, Tabriz, 1388.

Public title

The effect of continuity of midwifery care during labor on child birth Outcomes in patients referring to 29 Bahman hospital, Tabriz, 1388.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Parity lowers than 5; normal pregnancy (without multiple pregnancies, fetus and placental problems...); lack of internal – surgical affliction in mother; no distress in fetus; normal pelvic diameters (by vaginal examination); lack of psychological disorders and communication barriers in mother; lack of drug abuse in mother; being in active phase of labor; lack of cesarean section in history; maternal age 18 – 35; viable and term

fetus; estimated body weight in fetus lower than 4000 germs; without premature rupture of membranes and abnormal vaginal bleeding and willing to participate in the study Exclusion criteria: Client's changing mind from continuity of care; fetal distress; emergency problems for mother such as placental abruption.

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
Primary sampling from the society by non- probability sampling (convenience) and allocation of the samples in two groups by simple random sampling

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Science

Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan

City
Tabriz

Postal code

Approval date
2008-12-16, 1387/09/26

Ethics committee reference number
5/4/2421

Health conditions studied

1

Description of health condition studied
The effect of special manner of the midwifery cares offering in delivery stages on normal delivery outcomes

ICD-10 code
O36.9

ICD-10 code description
Maternal care for fetal problem, unspecified

Primary outcomes

1

Description
Kind of delivery

Timepoint
In first, second, third and fourth stage of delivery and childbirth

Method of measurement
Validated and reliable self administer check list for record the birth outcomes

2

Description
First and fifth minute neonate’s Apgar score

Timepoint
In first, second, third and fourth stage of delivery and childbirth

Method of measurement
Validated and reliable self administer check list for record the birth outcomes

3

Description
Length of first and second stage of labor

Timepoint
In first, second, third and fourth stage of delivery and childbirth

Method of measurement
Validated and reliable self administer check list for record the birth outcomes

4

Description
Induced (episiotomy) and spontaneous tears in perinea and vagina

Timepoint
In first, second, third and fourth stage of delivery and childbirth

Method of measurement
Validated and reliable self administer check list for record the birth outcomes

Secondary outcomes

1

Description
Uterus atonia in fourth stage

Timepoint
In first, second, third and fourth stage of delivery and childbirth

Method of measurement
Validated and reliable self administer check list for record the birth outcomes

2

Description
Method of membranes rupture
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

3

Description
Amount of used Oxytocine in labor
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

4

Description
Neonate’s gender and body weight
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

5

Description
Client’s fertility characteristics
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

6

Description
Fetal heart rates pattern in labor
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

7

Description
Uterus contractions pattern in labor
Timepoint
In first, second, third and fourth stage of delivery and childbirth
Method of measurement
Validated and reliable self administer check list for record the birth outcomes

Intervention groups

1

Description
In conventional care group: the clients (from admission time in delivery part till one hour after delivery), will care by a group of duty midwives, visit regularly at 1:30–2 hour intervals, in admission, labor and delivery sections. In this group, continuity and continuous presence of caregiver will not present.
Category
Other

2

Description
In continuity of care group: the clients will care by one midwife from admission time in delivery part till one hour after delivery. This midwife will not leave client's bedside for more than a few minutes. The caregiver(midwife) will offer midwifery care in labor; will perform delivery and all postpartum cares. The caregiver will remain in parturient's bedside, when she is examining by on call obstetrician and will perform all of the physician’s orders.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz, 29 Bahman hospital
Full name of responsible person
Fahimeh Sehhatie Shafaie
Street address
Nursing & midwifery faculty of Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mir Ali Eateraf Oskui
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Uroumieh University of Medical Sciences
Full name of responsible person
Maryam Najarzadeh
Position
Master in midwifery
Other areas of specialty/work
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Shahid Rasi hospital, Shahid Dast Geyb Street, Pasdaran Avenue, Shahindezh, West Azerbaijan
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Mmedical Sciences
Full name of responsible person
Fahimeh Sehhatie Shafaie
Position
Master in midwifery, Instructor of Tabriz nursing & midwifery faculty
Other areas of specialty/work
Street address
Tabriz nursing & midwifery faculty, South Shariaty Street, Shariaty Avenue, Tabriz, East Azerbaijan
City
Tabriz
Postal code
Phone
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty