Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of using admission protocol in normal childbirth on labour process, interventions and maternal and infant outcome

Protocol summary

Summary

A single -blind controlled clinical trial will be conducted to assess the impact of the admission protocol on the labor process, interventions and maternal and new-born outcome in normal childbirth. Participants are low risk women and first time mothers. They randomly will be allocated in two intervention and control group based on table of random figure. Women in the intervention group will be admitted using protocol and in the control group will be admitted by midwives and doctors clinical judgment.The protocol implies a set of rules and regulations to identify the active phase and women's admission to labor at this time. The protocol of admission in labour is developed using evidence-based medicine resources. The protocol included important clues about onset of labour and will be used to identify the active phase in order to admit women in labour. In the control group, admission assessment will be only based on clinical judgment of midwives or doctors. The main outcome measures of this study are duration of active phase, duration of second stage of labor, interventions (oxytocin use, rate of episiotomy) postpartum hemorrhage, method of delivery, average time of admission to discharge, Apgar score, admission to neonatal ward or NICU and mother's childbirth satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112225051N1**
Registration date: **2017-08-27, 1396/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-27, 1396/06/05

Registrant information

Name
Farzaneh Pazandeh
Name of organization / entity
Shahid Beheshti Medical Univerisity
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Recruitment status

Recruitment complete

Funding source

Chancellor of research Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using admission protocol in normal childbirth on labour process, interventions and maternal and infant outcome

Public title

The effect of using admission protocol in labour on labour process, interventions and maternal and infant outcome

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: low risk pregnant women without know medical condition; maternal age: 18-35 years old; first pregnancy; singleton pregnancy; gestational age 38-42 weeks; vertex presentation; regular fetal heart rate; normal BMI (25-19); normal implantation of placenta; no CPD; no history of surgical treatment on uterus; no substance abuse (tobacco, alcohol, heroin, glass); Newborns have no known medical conditions; no congenital abnormalities; no IUGR and macrosomia. Exclusion criterion: Vaginal bleeding more than normal and temperature up to 37/8 ° in admission

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: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitee of Shahid Beheshti University of Medical Sciences

Street address
Medical Sciences University of Shahid Beheshti Nursing and Midwifery faculty of Shahid Behshti, Vali Asr intersection prayer in front of the Rajai Hospital Beheshti Department of Nursing and Midwifery

City
Tehran

Postal code
1985717443

Approval date
2015-11-03, 1394/08/12

Ethics committee reference number
SBMU2.REC.1394.160

Health conditions studied

1

Description of health condition studied
Relationship between use of protocol of admission process in labor and labor process, interventions and maternal and infant outcom

ICD-10 code
080

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Method of birth

Timepoint
After of delivery

Method of measurement
Observation and record in check list

Secondary outcomes

1

Description
Number of hospital visits

Timepoint
Site visits to admission

Method of measurement
Of enter to hospital to discharge or admission

2

Description
Number of vaginal examinations

Timepoint
During first stage of normal labour

Method of measurement
Observation, record in check list

3

Description
Use of continuous electronic fetal monitoring

Timepoint
During first stage of normal labor

Method of measurement
Observation, record in check list

4

Description
Medication and analgesics used during labor

Timepoint
During first and second stage of normal labor

Method of measurement
Observation, record in check list

5

Description

Use of fundal pressure

Timepoint

During second stage of normal labor

Method of measurement

Observation, record in check list

6

Description

Length of Postnatal Stay

Timepoint

During the fourth stage of labo

Method of measurement

Measurement by Digital chronometer, to record in check list

7

Description

Perineal and vaginal tears

Timepoint

After of delivery

Method of measurement

Observation, clinical examination, record in check list

8

Description

Unplanned out-of-Hospital Birth

Timepoint

After of delivery

Method of measurement

Observation, record in check list

9

Description

Apgar score

Timepoint

1 and 5 minute after of delivery

Method of measurement

Observation, record in check list

10

Description

Newborn admission to NICU

Timepoint

After of delivery

Method of measurement

Observation, record in check list

11

Description

Postpartum hemorrhage

Timepoint

After childbirth

Method of measurement

Measurement of HG and HCT level by blood sampling 24 h after childbirth

12

Description

Mother’s satisfaction of childbirth

Timepoint

Before discharging of hospital

Method of measurement

Macky satisfaction questionnaire

13

Description

Artificial rupture of membrane

Timepoint

In Latent phase before complete of dilatation

Method of measurement

Observation, record in check list

14

Description

Length of labour

Timepoint

admission time to delivery

Method of measurement

Measurement by Digital chronometer, to record in check list

15

Description

Length of first stage of labor

Timepoint

Since the onset of labor pains to full dilation of the cervix

Method of measurement

Clinical examination, Measurement by digital chronometer, record in check list

16

Description

Length of second stage of labor

Timepoint

Complete dilatation to full embryo excretion

Method of measurement

Clinical examination, Measurement by digital chronometer, record in check list

17

Description

Length of the third stage of labor

Timepoint

full embryo excretion to full placenta excretion

Method of measurement

Observation, clinical examination, record in check list

18

Description

Use of oxytocin during labor

Timepoint

During first and second stage

Method of measurement

Observation, record in check list

Intervention groups

1

Description
Intervention group: A protocol for admission in labour will be used for the intervention group. The protocol consisted of the following key information for diagnosing of active phase: a.Existence regular uterine contractions (3-5 contractions in 10 minutes takes 40-60- seconds) b. Dilation of cervix ≥ 4 cm c. Existence of rupture of membrane, or bloody show. d. Women who did not have these signs will be returned to their home. Women will be given awareness regarding danger signs. They will contact the hospital in the case of any problem. e. If there is a long distance problem or mother has intense anxiety, women will be stayed in a special place in hospital which has been designed for this purpose. The emotional support will be given to them.
Category
Other

2

Description
Control group: The admission of this group of participant women in labour will be solely based on the clinical judgment of midwives or doctors.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Yahya Nejad Hospital
Full name of responsible person
Freshteh Abasian
Street address
Modares street, Mostafa khomainy street, Babol, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Besides of Taleghani Hospital, Shahid Aarabi Street, Yaman Street, Shahid Chamran Highway
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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
Shahid Beheshti 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

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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