

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of physiological birth on mother and newborn health

Protocol summary

Summary

Objective: We aimed to determine the effect of physiological birth in outcomes of delivery, including duration of first, second and third stages of labour, amount of blood loss in the third and fourth stages of labour, perineal statue, delivery method, decolman, asphyxia, apgar score and satisfaction of birth. Methods: A randomised controlled trial was completed on 200 women who gave birth at Akbar Abadi hospital in Tehran, Iran. 100 were allocated to physiological birth (intervention group) and 100 to routine vaginal birth (control group). Inclusion criteria included the following: gestational age between 37 and 42 weeks; singleton pregnancy; live fetus; cephalic presentation; neonatal birth weight estimation of 2500–4000 g; maternal age 18-45 years; and vaginal dilatation between 3 and 4 centimeter. The data collection instruments included three questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805062248N1**

Registration date: **2010-08-30, 1389/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-08-30, 1389/06/08

Registrant information

Name

Fereshteh Jahdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2009-07-29, 1388/05/07

Expected recruitment end date

2010-03-27, 1389/01/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of physiological birth on mother and newborn health

Public title

The effect of physiological bith on mother and newborn health

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria included the following: 1- gestational age between 37 and 42 weeks 2- singleton pregnancy 3- live fetus 4- cephalic presentation; neonatal birth 5- weight estimation of fetus : 2500–4000 g 6- maternal age 18-45 years 7- vaginal birth. Exclusion criteria included the following: 1- Blood pressure <140/90mmHg 2- Placenta previa 3- A history of caesarean section or any uterine scar 4- Polyhydramnios 5- Prolonged rupture of membranes

Age

From **18 years** old to **45 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

School of nursing and midwifery, Iran University of Medical Sciences

Street address

Valiasr Ave. Rashidyasemi Ave.

City

Tehran

Postal code

Approval date

2009-07-20, 1388/04/29

Ethics committee reference number

1323583

Health conditions studied

1

Description of health condition studied

Physiological Birth

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Duration of the first stage of labor

Timepoint

cervix dilatation from 4 centimeter to 10 centimeter

Method of measurement

Digital chronometer

2

Description

Duration of the second stage of labor

Timepoint

Cervix dilatation from 10 centimeter to fetus expulsion

Method of measurement

Digital chronometer

3

Description

Duration of the third stage of labor

Timepoint

From completed delivery of the fetus to completed delivery of the placenta

Method of measurement

Digital chronometer

4

Description

The amount of blood loss during the third stage of labour

Timepoint

Third stage of labour

Method of measurement

Scaled dish

5

Description

The amount of blood loss during the third stage of labour

Timepoint

Third stage of labour

Method of measurement

Scaled dish

6

Description

The amount of blood loss during the forth stage of labour

Timepoint

Forth stage of labour

Method of measurement

Scaled dish

Secondary outcomes

1

Description

Decolman

Timepoint

First stage of labor

Method of measurement

Obsevation and record in questionnaire

2

Description

Asphyxia

Timepoint

First and second stage of labor

Method of measurement

Obsevation and record in questionnaire

3

Description

Perineal statue

Timepoint

After delivery of placenta

Method of measurement

Obsevation and record in questionnair

4

Description

Method of delivery

Timepoint

After delivery of fetus

Method of measurement

Obsevation and record in questionnair

5

Description

Apgar score

Timepoint

1 and 5 minute

Method of measurement

Obsevation and record in questionnaire

6

Description

Satisfaction of delivery

Timepoint

Before discharging of hospital

Method of measurement

Macky satisfaction questionnaire

Intervention groups

1

Description

Intevention: physiological birth

Category

Prevention

2

Description

Control group: Rutine normal delivery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abaadi hospital

Full name of responsible person

Maryam Shahnazari Avval

Street address

Molavi street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, vice chancellor for research

Full name of responsible person

Dr. Motevalian

Street address

Hemmat High way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences, vice chancellor for research

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

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

Maryam shahnazari Avval

Position

Master in midwifery

Other areas of specialty/work

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Fax**Person responsible for updating data****Contact****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