

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Effect of water immersion during the first stage of labor on pain and the outcome of labor of primipara women attending to Khaleej-e fars hospital in Bandar Abbas

Protocol summary

Summary

(1) Objectives: The aim of this study is to determine the effects of immersion in water in the first stage of labor, on the pain intensity and the consequences of labor and delivery. (2) Design: This is a clinical trial that will be conducted in two intervention and control groups and after obtaining informed consent the subjects randomly will assign to two groups which 100 persons in each group will allocate. (3) Setting and conduct: Subjects of intervention group from the active phase of labor (cervical dilatation 4 cm) until the end of the first stage (full dilation of the cervix), will immerse in a special ceramic tub full of water with a temperature of 37 to 37.5 degrees Celsius (water should be up to 2 cm above the nipple of mother) and at this time progress of labor and fetal heart rate will assess. VAS (Visual Analog Scale) will be use for measuring pain intensity during labor. With the start of second stage of labor, mother will exist from the water and will transfer to the labor room. In control group routine care including labor and fetal heart rate evaluation without using any methods of pain relief during labor according to country protocol will done. (4) Inclusion criteria include: nulliparous with term and singleton pregnancy; active phase of labor (4 cm cervical dilatation); vertex presentation; not having any underlying medical problems; maternal age between 35-18; normal BMI; normal NST; attend in preparation for childbirth classes. (5) Intervention: Immersion in water during labor (6) Main outcome measures (variables): Comparison of labor pain intensity, duration of first stage of labor and mode of delivery two groups will compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111725002N2**

Registration date: **2016-01-12, 1394/10/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-12, 1394/10/22

Registrant information

Name

Fatemeh Dabiri

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

fatemehdabiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of water immersion during the first stage of labor on pain and the outcome of labor of primipara women

attending to Khaleej-e- fars hospital in Bandar Abbas

Public title
The impact of water birth on childbirth

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Nulliparous women; Age 35-18 years; Height over 150 cm; BMI 18.5-24.9; Singleton pregnancy; Gestational age 37-40; Participation in preparation for childbirth classes; Vertex presentation; Alive fetus; Not having risk factors (abnormal vital signs of mother- of mother underlying disease- prolonged rupture of membrane- vaginal bleeding, oligo or polyhydramnios- placenta previa- placental abruption- meconium-stained- intrauterine growth restriction- fetal macrosomia- abnormal fetus- History of infertility); Regular uterine contractions; 4 cm cervical dilatation; Normal NST; Mother's consent to participate in research. Exclusion criteria: Abnormal fetal heart rate changes; abnormal changes in vital signs of mother; Abnormal vaginal bleeding during labor; meconium passage by fetus during labor; requirement to any medical intervention for pregnant of mother during labor; unwillingness to continue to participate in research

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Hormozgan University of Medical Sciences, Shahid Chamran BLV. Bandar Abbas, Iran

City
Bandar Abbas

Postal code

Approval date
2015-11-18, 1394/08/27

Ethics committee reference number
HUMS.REC.1394.87

Health conditions studied

1

Description of health condition studied

Labor pain

ICD-10 code

080

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

labor pain intensity

Timepoint

before intervention then every hour until get out of water

Method of measurement

Visual Analog Scale

2

Description

The duration first stage of labor

Timepoint

The time from 4 cm cervical dilatation to complete dilation of the cervix

Method of measurement

Time in Minutes

3

Description

The length of second stage of labor

Timepoint

The time between full dilatation of cervix and fetal expulsion

Method of measurement

Time in minute

Secondary outcomes

1

Description

perineum status

Timepoint

after delivery

Method of measurement

Intact/episiotomy/laceration

2

Description

Apgar Score

Timepoint

1 and 5 minutes after birth

Method of measurement

numeric

Intervention groups

1

Description

In the intervention group, mother in the active phase of labor will enter into the tub full of water with the appropriate temperature in order to investigate the effects of immersion in water on the duration and intensity of labor. Labor pain intensity will evaluate by using the VAS before entering the water and then every hour until exiting from water. Mother will remain in water all of the first stage of labor. The duration of first stage of labor will calculate in minutes from 4 cm cervical dilatation to fully cervical dilatation. Mother will have no restrictions on eating and drinking. Finally, the results will be compared with the control group.

Category

Other

2

Description

In the control group: routine care, labor control will perform and will not use any method of pain reduction during labor. Mother will have no limitation on choice of positions during labor. Labor pain intensity will evaluate by using the VAS every hour until full dilatation of cervix. The duration of first stage of labor will calculate in minutes from 4 cm cervical dilatation to fully cervical dilatation. Mother will have no restrictions on eating and drinking. Finally, the results will be compared with the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalije Fars Hospital

Full name of responsible person

Fatemeh Darsare

Street address

Khalije Fars Hospital, Pardis BLV, Bandar Abbas

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research ,Hormozgan University of Medical Sciences.Mother & Child Welfare resear

Full name of responsible person

Asieh Pormehr Yabandeh

Street address

Vice Chancellor for Research,Hormozgan University of Medical Sciences. Shahid Mohammadi Hospital,Jomhoori BLVe,Bandar Abbas, Iran.

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research ,Hormozgan University of Medical Sciences.Mother & Child Welfare resear

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

Hormozgan University of Medical Sciences

Full name of responsible person

Fatemeh Dabiri

Position

PhD student of reproductive Health, Faculty member

Other areas of specialty/work

Street address

Nursing & Midwifery collage,Resalat Ave,

City

Bandar Abbas

Postal code

Phone

+98 76 3366 6367

Fax

Email

fatemehdabiri@sbmu.ac.ir; fateme.dabiri@hums.ac.ir;

fateme.dabiri @gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Fatemeh Dabiri

Position

PhD student

Other areas of specialty/work

Street address

Nursing & midwifery collage, Resalat Avenue

City

Bandar Abbas

Postal code

Phone

+98 76 3366 6367

Fax

Email

fatemehdabiri@sbmu.ac.ir; fateme.dabiri@hums.ac.ir;
fateme.dabiri@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Fatemeh Darsare

Position

Other areas of specialty/work

Street address

City

Bandar Abbas

Postal code

Phone

00

Fax

Email

famadarsareh@yahoo.com

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