Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of maternal and fetal/neonatal outcomes of water birth and land birth in mothers hospitalized in labor wards of selected hospitals of Isfahan in 1404

Protocol summary

Study aim

1. comparing average pain intensity score of the first and second stages of labor in two groups 2. comparing average duration of first, second, and third stages of labor in two groups 3. comparing average postpartum hemorrhage volume in two groups 4. comparing frequency of perineal rupture in second stage of labor in two groups 5. comparing frequency of postpartum uterine or urinary tract infection in two groups 6- comparing Apgar score of first and fifth minutes of the newborn in two groups 7. comparing frequency of hospitalization of the newborn in NICU in two groups 8- comparing frequency of shoulder dystocia in two groups 9. comparing frequency of snapped cord in two groups

Design

clinical trial with two groups of control (land delivery) and intervention(water delivery) , with parallel groups; single blinded; randomized by sealed, opaque packets by random selection; on 66 multiparous women

Settings and conduct

In maternity wards of Asgariyah Hospital, multiparous women will be taken to bath-tub to undergo their labor and delivery. Participants will not be blinded.

Participants/Inclusion and exclusion criteria

-Iranian nationality with at least elementary literacy - Singleton full-term pregnancy -Cephalic presentation - Cephalo-pelvic proportion - Absence of any abnormal pattern of fetal heart rate at the time of study entry - Estimated newborn weight 4000-2500 grams

Intervention groups

Intervention involved taking mothers into a tub of warm water to undergo labor and delivery in the water.

Main outcome variables

Maternal outcomes : pain intensity during the first and second stages of labor; duration of the first, second, and third stages of labor; volume of postpa and postpartum uterine or urinary tract infection. Fetal/neonatal outcomes: neonatal Apgar; shoulder dystocia; umbilical cord rupture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091001002531N8**
Registration date: **2026-08-05, 1405/05/14**
Registration timing: **prospective**

Last update: **2026-08-05, 1405/05/14**
Update count: **0**

Registration date

2026-08-05, 1405/05/14

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-20, 1405/05/29

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of maternal and fetal/neonatal outcomes of water birth and land birth in mothers hospitalized in labor wards of selected hospitals of Isfahan in 1404

Public title

maternal and fetal/neonatal outcomes of water birth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

vaginal bleeding Term singleton pregnancy with cephalic presentation Not having obvious cephalopelvic disproportion Not having any fetal heart rate disorders and meconium excretion when entering the study Optimal non-stress test estimated weight of fetus 2500-4000 grams Not having sever IUGR or absence of placenta grading 3 or more Not having asthma, glaucoma, tuberculosis, adrenal insufficiency and hepatitis Not having active genital herpes, HIV and genital herpes having no psychological disorders based on the statements of the mother/companions and medical documents not having fever and history of caesarean section No oxytocin infusion Not having heart diseases, blood pressure, pre-eclampsia, multiple sclerosis, overt or gestational diabetes, rheumatism not having placenta previa , myoma, uterine abnormality, or fetal abnormality intact amniotic sac mothers age 18-40 BMI less than 30 Not taking herbal medicines to induce labor during 24 hours before induction (such as saffron and cumin) Signing the consent form Iranian nationality

Exclusion criteria:

non satisfying pattern of FHR or meconium excertion during study applying vacuum for head pulling the occurrence of cesarean section Mother's unwillingness to continue participating in the study The occurrence of any problem that deviates from the normal course of labor, such as bleeding, maternal fever or hypertension

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate the participants to two group (land birth and water birth) randomly, the researcher will ask mothers to take a sealed opaque package out of 80 randomly. 40 packages contains questionnaires and checklists coded 1(related to land birth group) and 40 packages contains the same questionnaires and checklists coded 2(related to water birth group). It will be written code 1 or code 2 instead of land birth or water birth on the questionnaires and checklists in order to the data analyzer could be blinded. This process will continue until having at least 34 samples in both groups. In this way, concealment of randomization will be performed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Please describe who is blind in your study and how you have achieved this. The conventional terms of single, double and triple blinds are not informative in some occasions and you need to describe in detail how people who are involved in your study are blinded. A full description of blinding should have statements on the following groups of people involved in the trial: participants, principle investigator particularly in investigator initiated trials, healthcare providers (Physicians, nurses, physiotherapists, etc.) who care for participants during the trial, data collectors, outcome assessors, and with lessor importance Data Safety and Monitoring Board and manuscript writers

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Schools of Nursing, Management, and Rehabilitation, Isfahan University

Street address

Midwifery and Reproductive Health Department, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

8174673

Approval date

2026-07-07, 1405/04/16

Ethics committee reference number

IR.MUI.NUREMA.REC.1405.053

Health conditions studied

1

Description of health condition studied

maternal Complications of labour and delivery such as pain, postpartum hemorrage, ...

ICD-10 code
O60-O75
ICD-10 code description
Complications of labour and delivery

Primary outcomes

1

Description
severity of pain of avtive phase of the first stage of delivery
Timepoint
During the first two hours after delivery, as soon as the mother is ready.
Method of measurement
visual analoge scale

2

Description
severity of pain of avtive phase of the first stage of delivery
Timepoint
During the first two hours after delivery, as soon as the mother is ready.
Method of measurement
visual analoge scale

3

Description
duration of active phase of the first stage od delivery
Timepoint
When cervical dilation reaches 10 centimeters
Method of measurement
kornometere

4

Description
duration of the second stage od delivery
Timepoint
As soon as the baby is born
Method of measurement
kornometere

5

Description
duration of the third stage od delivery
Timepoint
As soon as the placenta comes out
Method of measurement
kornometere

6

Description
volume of bleeding after delivery
Timepoint
during third and fourth stage of delivery (frome birth of newborn untill one hour afer placental delivery)
Method of measurement
Weighing the sheets before and after changing

7

Description
tear of perinium in second stage of delivery
Timepoint
just after placenta delivery
Method of measurement
observation

8

Description
infections of mother during one week after delivery
Timepoint
one week after delivery
Method of measurement
asking the mother

9

Description
APGAR score neonate
Timepoint
one and 5 minutes after birth
Method of measurement
apgar score scale

10

Description
hospitalization of newborn in neonatal intensive care unit
Timepoint
one week after birth
Method of measurement
hospital record

11

Description
infectious diseases of newborn during 0ne week after birth
Timepoint
one week after birth
Method of measurement
asking the mother

12

Description
shoulder dysticia
Timepoint
During the baby's shoulder protrusion
Method of measurement
observation

13

Description
Umbilical cord snap during childbirth
Timepoint
In the time between the birth of the baby and the

expulsion of the placenta

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At onset of the active stage of delivery (minimum dilation of cervix 5 cm), the parturient mothers enter a warm tub to undergo labor and give birth in water.

Category

Other

2

Description

Control group: The mothers undergo their labor in bed or out of bed. then they give birth in bed on lithotomy position as usual routin.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Askarieh Hospital

Full name of responsible person

Dr. Mohammad-reza Shah-Naser

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Asgariye street

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Isfahan

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Isfehan

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8199753966

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Email

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Web page address

https://askariehospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholam-reza Askari

Street address

Hezar-jerib

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Isfehan

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Email

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Web page address

https://research.mui.ac.ir/fa

Grant name

Grant code / Reference number

2404203

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Tahmineh Dadkhahtehrani

Position

academic member

Latest degree

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Other areas of specialty/work

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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