# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effects of perineal massage in active phase on delivery outcomes in nulliparous women

## Protocol summary

**Summary**

This study was conducted with the aim to investigate the effectiveness of perineal massage on birth outcomes, as a single-blind randomized clinical trial in 140 primiparous healthy women with full term pregnancies. Sample size 140 (70 massage and 70 control group). Continuous sampling method with random selection was conducted. Subjects with Prolonged second stage of labor, precipitate labor, shoulders dystocia, or cephalo pelvic dyspropotion were excluded. Questionnaire and code shits were used for data collection. In massage group in the active phase of labor with the head in the stage of Zero (head of schial spine which is in mid pelvic) and cervical dilatation 6-7 cm, which is measured with fingers. Pointing finger and middle fingers were dipped in a lubricating substance (Key jell) and admitted in the vagina of the parturing women and slidered to the size of fingers 5-4 cm between 3to 9 O' clock alternatively.Women who decided not to have continue massage was stopped. After delivery, code shits questions (second stage of labor, episiotomy and perineal tear degree) were completed in both groups. In the third and tenth days in postpartum the subjects were contact code shits questions ( severity of perineal pain in the third and tenth day after delivery) were completed. Urinary stress incontinence and focal incontinence in the three mounth after delivery were completed

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201111053034N8**
Registration date: **2012-07-21, 1391/04/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-07-21, 1391/04/31

**Registrant information**

**Name**
Mansoureh Jamshidimanesh
**Name of organization / entity**
Iran University Faculty of Nursing & Midwifery
**Country**
Iran (Islamic Republic of)
**Phone**
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research,Tehran University of Medical Sciences

**Expected recruitment start date**

2009-08-01, 1388/05/10

**Expected recruitment end date**

2010-03-21, 1389/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of perineal massage in active phase on delivery outcomes in nulliparous women

**Public title**

The effects of perineal massage on delivery outcome

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Iranian; no lesions on genitalia absence

of any kind of diseases; no sign of preeclampsia or eclampsia; live fetus; cephalic; singleton; maternal age 18-35; no dysparonia; no UTI and no practice during pregnancy. Exclusion criteria: Subjects with Prolonged second stage of labor; precipitate labor (Labor that results in rapid expulsion of the fetus); pervious deliver by forceps of vacuum; Cesarean section; shoulders dystocia; or cephalo pelvic disproportion (c.p.d.); last baby weight less than 2500 kgr; And more than 4000 kgr; any change on address and telephone number were excluded.

**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: **140**

**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,Tehran University of Medical Sciences

**Street address**
School of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid field, Nosrat-e SHarghi avenue

**City**
Tehran

**Postal code**

**Approval date**
2009-07-21, 1388/04/30

**Ethics committee reference number**
1323573

## Health conditions studied

### 1

**Description of health condition studied**
During the second stage of labor

**ICD-10 code**
063

**ICD-10 code description**
prolong second stage of labor

### 2

**Description of health condition studied**
Episiotomy

**ICD-10 code**
070

**ICD-10 code description**
episiotomy extended by laceration

### 3

**Description of health condition studied**
Perineal outcomes

**ICD-10 code**
070.0,070.

**ICD-10 code description**
Fourth degree perineal laceration during delivery,Third degree perineal laceration during delivery,Second degree perineal laceration during delivery,First degree perineal laceration during delivery

### 4

**Description of health condition studied**
Urinary stress incontinence

**ICD-10 code**
N39.3

**ICD-10 code description**
Use additional code (N32.8), if desired, to identify overactive bladder or detrusor muscle hyperactivity

### 5

**Description of health condition studied**
Fecal incontinence

**ICD-10 code**
M62.9

**ICD-10 code description**
Disorder of muscle, unspecified

### 6

**Description of health condition studied**
Intensity perineal pain

**ICD-10 code**
N39.3

**ICD-10 code description**
Complication of labour and delivery, unspecified

## Primary outcomes

### 1

**Description**

Focal incontinence

**Timepoint**

Three months after delivery.

**Method of measurement**

Question

**2**

**Description**

Urinary stress incontinence

**Timepoint**

Three months after delivery.

**Method of measurement**

Question

**3**

**Description**

Perineal out come

**Timepoint**

after intervention

**Method of measurement**

observation

**4**

**Description**

During the second stage of labor

**Timepoint**

after prevention

**Method of measurement**

Examination

**5**

**Description**

Intensity perineal pain

**Timepoint**

3 day and 10 day after delivery

**Method of measurement**

visual analouge scale

**6**

**Description**

Episiotomy

**Timepoint**

after delivery

**Method of measurement**

observation

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

The researcher in the massage group out of sight and assist researchers in the active phase of labor and fetal head descent in the supine position and the zero position of 7-6 cm cervical dilatation until delivery, after-stained index finger and middle finger to the slider

**Category**

Prevention

**2**

**Description**

The control group with no intervention other than routine measures failed.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Dr.Ali Gravnd

**Street address**

Imam Khomeini hospital, Field Keshavarz, Sepah Avenue, Kuhdasht city, Kohdasht, lorestan

**City**

Kuhdasht

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research,Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Cheraghi

**Street address**

School of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid field, Nosrat-e SHarghi avenue

**City**

Tehran

**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,Tehran 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**
Khuhdasht Health Network
**Full name of responsible person**
Amene piri Galledar
**Position**
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## Person responsible for updating data

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**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*