

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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 shifts 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 shifts 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 shifts 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)

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+98 21 4365 1811

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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 dyspareunia; 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); previous delivery by forceps or 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

Kuhdasht Health Network

Full name of responsible person

Amene piri Galledar

Position

MSc Midwifery, Master of Science

Other areas of specialty/work

Street address

Health Network, Farmandari Field, Imam Khomeini Avenue, Kuhdasht city

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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