Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of preineal massage in second stage of labor on preineal trauma, episiotomy and its outcomes among nuliparous women referred to delivery ward of Beasat hospital, 2013.

Protocol summary

Summary

The aim of this study is determine the effect of prineal massage in second stage of delivery on prineal trauma, episiotomy and its outcome in nuliparous women referred to delivery ward of Beasat hospital of Sanandaj. This is a clinical trial. Inclusion criteria: Nuliparity with gestational age 38-42 weeks, singleton, cephalic presentation, without PROM, placenta abruption , cephalo pelvic disproportion, fetal distress, do not have vaginal infections and herpes, do not have kegel exercise and professional sport. Exclusion criteria: failure in progress, fetal distress, getting sedative, getting oxytocin , having operative delivery, being red rush and prineal edema,mother request for disconnect the massage , need to cesarean, shoulder dystocia, occiput posterior, baby more than 4000 gram or below 2500. During second stage of childbirth the researcher put gloves and with two fingers with sterile jell massage area between 3 to 9 point of perineal. After child birth tear of perineal, episiotomy rate will be assessed among two groups.. Perineal pain and its intensity 3, 10 days and 3 months after child birth will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090314556N1**
Registration date: **2013-11-10, 1392/08/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-11-10, 1392/08/19

Registrant information

Name

Roonak Shahoei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preineal massage in second stage of labor on preineal trauma, episiotomy and its outcomes among nuliparous women referred to delivery ward of Beasat hospital, 2013.

Public title

The Effect of Prineal Massage on Prineal Trauma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: nuliparity with gestational age 38-42 weeks; singleton; cephalic presentation; without PROM;

placenta abruption; cephalo pelvic disproportion; fetal distress; do not have vaginal infections and herpes; do not have kegel exercise and professional sport. Exclusion criteria: failure in progress; fetal distress; getting sedative; getting oxytocin; having operative delivery; being red rush and prineal edema; mother request for disconnect the massage; need to cesarean; shoulder dystocia; occiput posterior; baby more than 4000 gram or below 2500.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kurdistan University of Medical Sciences

Street address
Sanandaj - Kurdistan _ Iran

City
Sanandaj

Postal code
66166

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
muk.rec.1392.17

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
O80

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Doing episiotomy

Timepoint
During delivery

Method of measurement
Clinical examination

2

Description
Safe prieneal

Timepoint
During delivery

Method of measurement
Prieneal examination

Secondary outcomes

1

Description
Prineal trauma

Timepoint
After delivery

Method of measurement
Clinical examination

2

Description
Prineal pain

Timepoint
3 and 10 days after delivery and 3 months after delivery

Method of measurement
Pain questioner

Intervention groups

1

Description
There is not any intervention for control group and after child birth perineal and vagina will be checked and determined perineal rupture and episiotomy rate. Post natal care will be performed for all mothers. For assessing perineal pain and its intensity all mothers will be followup 3 and 10 days during post postpartum.

Category
Treatment - Drugs

2

Description
Researcher during second stage of childbirth (from full dilatation till expulsion of fetal head) put gloves and with

K vay Jell , perineal will be massage between 3 and 9 area of vagina gently for 30 minutes. After childbirth perineal will be checked for rupture and episiotomy rate. During postpartum , 3 and 10 days after birth mother will be evaluated for perineal pain and its intensity.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and treatment Beasat Center, Sanandaj

Full name of responsible person

Roonak Shahoei

Street address

Sanandaj - Kurdistan _ Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Haidary

Street address

Sanandaj - Kurdistan _ Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan 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

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Roonak Shahoei

Position

PhD

Other areas of specialty/work

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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