

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of perineal massage during pregnancy on perineal trauma and postnatal pain among women referred to Beasat Hospital, Sanandaj

Protocol summary

Summary

This study is clinical trial triple blind. The research community are pregnant women who referred to delivery ward of Besat hospital in Sanandaj. Case group are women with 38 -42 weeks of gestational age who had preneal massage from 34 weeks of pregnancy according to massage education. Control group are women who did not have any preneal massage during pregnancy. Inclusion criteria are: pregnant women with gestational age between 38-42 weeks, singleton, cephalic who refereed to delivery ward of Beaset hospital in Sanandaj and had perineal massage from 34 week of pregnancy. Exclusion criteria are: multiple pregnancy, cesarean history, using forceps or vacuum for delivery,using oxytocin, shoulder dystocia, occiput posterior, macrosomy, preterm rupture of membranes, pelvic dystocia, placenta abruption, fetal distress, using sedative and failure of progress. Sampling method is convenience sampling. The aim of study is survey of the effect of perineal massage during pregnancy on perineal trauma and postnatal pain among women referred to Beasat Hospital, Sanandaj.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011814556N2**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Roonak Shahoei

Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical sciences

Expected recruitment start date

2014-04-05, 1393/01/16

Expected recruitment end date

2016-01-06, 1394/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of perineal massage during pregnancy on perineal trauma and postnatal pain among women referred to Beasat Hospital, Sanandaj

Public title

The effect of perineal massage during pregnancy on perineal trauma and postnatal pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are: pregnant women with gestational age between 38-42 weeks, singleton, cephalic who refereed to delivery ward of Beaset hospital in Sanandaj and had perineal massage from 34 week of pregnancy. Exclusion criteria are: multiple pregnancy, cesarean

history, using forceps or vacuum for delivery, using oxytocin, shoulder dystocia, occiput posterior, macrosomy, preterm rupture of membranes, pelvic dystocia, placenta abruption, fetal distress, using sedative and failure of progress.

Age

From **14 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Single

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

2014-03-05, 1392/12/14

Ethics committee reference number

14/47256

2

Ethics committee

Name of ethics committee

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Postal code

66166

Approval date

2014-03-05, 1392/12/14

Ethics committee reference number

14/47256

Health conditions studied

1

Description of health condition studied

perineal complication

ICD-10 code

070

ICD-10 code description

Primary outcomes

1

Description

perineal tear

Timepoint

after delivery

Method of measurement

using questioner and examination after delivery

Secondary outcomes

1

Description

perineal pain

Timepoint

3 and 10 days after delivery and 3 months after delivery

Method of measurement

pain questioner

Intervention groups

1

Description

First of all researcher selected one of the midwife who work in best hospital as co worker and teach her about preneal massage , choosing sample , filling consent form and questioner. Then co-worker teach the case group about preneal massage and will wanted them to use this massage from 34 weeks of pregnancy every day for 8 minutes in the shape of U between 3 to 9 clock of vagina with olive oil.

Category

Prevention

2

Description

There is not any instruction and recommend for preneal massage during pregnancy for control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kurdistan University of Medical Sciences
Full name of responsible person
Roonak Shahoei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Dr Haidary
Street address
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Sanandaj
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

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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