

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effects of lidocaine pomade , indomethacin suppository and mefenamic acid on the relief of post episiotomy pain in primiparous women

Protocol summary

Summary

The aim of this study is to compare the lidocaine pomade, Indomethacin suppository and mefenamic acid capsule on the pain of post episiotomy. The primiparous women with singleton pregnancy and 38-42 weeks of gestation will participate in the study. The sample size is ninety and the women will randomly allocated to three groups receiving the indomethacin, lidocaine and mefenamic acid . For data collection, we will use visual analogue scale to assess the severity of pain . At the time of arriving the women to post delivery ward, with complain of pain, the severity of perineal pain will detect and then the drugs will given. The first group will receive the 50 mg indomethacin, the second group will receive the lidocaine and the third group will receive the 250 mg mefenamic acid . Pain scores will assess in 2-6-12 and 24 hours after the delivery. If necessary ,we will repeat the drugs every 6-8 hours until 24 hours after the delivery .The drugs will administrated by the obstetrician and all of women will receive the standard prenatal care in three groups .Inclusion criteria are: medio-lateral episiotomy, length of episiotomy <5 cm, no forceps and vacuum, no currage and the equal of lidocaine infiltration for episiotomy .Exclusion criteria are: laceration of perineum, length of episiotomy >5 cm, use of forceps and vacuum, currage and inflammation of perineum

General information

Acronym

Episiotomy

IRCT registration information

IRCT registration number: **IRCT201104253078N7**

Registration date: **2011-07-15, 1390/04/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-15, 1390/04/24

Registrant information

Name

Masoumeh Delaram

Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research deputy , Shahrekord University of Medical Sciences

Expected recruitment start date

2011-05-31, 1390/03/10

Expected recruitment end date

2012-05-30, 1391/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of lidocaine pomade , indomethacin suppository and mefenamic acid on the relief of post episiotomy pain in primiparous women

Public title

The relief of post episiotomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria : The primiparous women with episiotomy
Exclusion Criteria : The primiparous women with episiotomy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

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**

The Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord -Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

-

Approval date

2011-06-28, 1390/04/07

Ethics committee reference number

9-4-90

Health conditions studied**1****Description of health condition studied**

Post Episiotomy Pain

ICD-10 code

O86.0

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes**1****Description**

Reduction of post episiotomy pain

Timepoint

2-6012 and 24 hours after delivery

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Patient satisfaction

Timepoint

At the end of intervention

Method of measurement

Question of women

Intervention groups**1****Description**

Group 1: The recipient of lidocaine pomad 2% on the episiotomy line and repeat every 6-8 hours until 24 hours after the delivery

Category

Treatment - Drugs

2**Description**

group 2: The recipient of 100 mg indomethacin suppository and repeat every 6-8 hours until 24 hours after the delivery

Category

Treatment - Drugs

3**Description**

Group 3: The recipient of 250 mg mefenamic Acid capsule and repeat every 6-8 hours until 24 hours after the delivery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hajar Hospital in Shahrekord

Full name of responsible person

Masoumeh Delaram

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masoumehdelaram@yahoo.com**Web page address**<http://www.skums.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Research Council Of Shahrekord University of Medical
Sciences**Full name of responsible person**

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Shahrekord

Grant name

466-71-01-1389

Grant code / Reference number

1389-01-71-466

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

Yes

Title of funding sourceResearch Council Of Shahrekord 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**

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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