

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the efficacy of Ibuprofen and Celecoxib on the intensity of perineal pain following episiotomy: a single blind, randomized clinical trial

Protocol summary

Summary

This randomized single-blind controlled trial was performed to compare the effectiveness of 2 analgesics for the management of perineal pain due to episiotomy. Methods: A total of 170 Nulliparous women who gave birth vaginally with episiotomy between March 2009 and November 2010 at a teaching hospital affiliated to ministry of health (shahid Mostafa Khomainsi hospital, Ilam, Iran) were randomly assigned to receive either ibuprofen (400 mg) (n = 85) or Celecoxib (100mg) (n = 85), ibuprofen and Celecoxib given orally every 6 and 12 hours, respectively, as necessary. Inclusion criteria: 1- 18-35 years old; 2-mediolateral episiotomy; 3-singleton; 4- alive fetus. Exclusion criteria: 1-sensitivity to NSAIDs; 2-history of digestive system disorders; 3-presence of chronic illness; 4-rupture of cervix; 5-post partum hemorrhage; 6-pre eclampsia and eclampsia; 7-PROM. Pain ratings were measured before intervention and at 1, 2, 4, 8 and 12 hours after the first dose on a 10-cm visual analogue scale (in resting and moving stages).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106136790N1**
Registration date: **2012-08-14, 1391/05/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Zainab Suhrabi

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 84 1222 7123

Email address

suhrabi-z@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology of Ilam University of Medical Sciences

Expected recruitment start date

2009-03-30, 1388/01/10

Expected recruitment end date

2010-10-29, 1389/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Ibuprofen and Celecoxib on the intensity of perineal pain following episiotomy: a single blind, randomized clinical trial

Public title

Comparing the efficacy of Ibuprofen and Celecoxib on the intensity of perineal pain following episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-18-35 y/o; 2-mediolateral episiotomy; 3-singleton; 4- alive fetus. Exclusion criteria: 1-sensitivity to NSAIDs; 2-history of digestive system disorders; 3-

presence of chronic illness; 4-rupture of cervix; 5-post partum hemorrhage; 6-pre eclampcia and eclampcia; 7-PROM.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **170**

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

Ilam University of Medical Sciences

Street address

Banganjab, Pajohesh Blvd

City

Ilam

Postal code

Approval date

2008-10-11, 1387/07/20

Ethics committee reference number

5195/40/22

Health conditions studied

1

Description of health condition studied

post episiotomy pain

ICD-10 code

O75.4

ICD-10 code description

Other complications of obstetric surgery and procedures

Primary outcomes

1

Description

pain severity

Timepoint

pre intervention,1, 2, 4, 8 and 12 hours after intervention

Method of measurement

VAS

Secondary outcomes

1

Description

Digestive system complications

Timepoint

Every 12 hours

Method of measurement

History and Physical exam

Intervention groups

1

Description

Ibuprofen (400 mg), every 6 and 12 hours as necessary

Category

Treatment - Drugs

2

Description

Celecoxib (100mg), orally, 6 and 12 hours as necessary

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomaini hospital

Full name of responsible person

Street address

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Morvat Taheri Kalani

Street address

Banganjab, Pagoohesh Blvd.

City

Ilam

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Zainab Suhrabi

Position

MSc of Midwifry/ faculty member

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