

# 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)

##### Phone

+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**

**Street address**

Banganjab,pajohesh BLvd.

**City**

Ilam

**Postal code**

**Phone**

+98 84 1222 7123

**Fax**

+98 84 1222 7123

**Email**

suhrabi-z@medilam.ac.ir ; suhrabi2007@yahoo.com

**Web page address**

## Person responsible for scientific 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**

**Street address**

Banganjab, Pajohesh Blvd.

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suhrabi-z@medilam.ac.ir ; suhrabi2007@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Zainab Suhrabi

**Position**

MSc of Midwifry

**Other areas of specialty/work**

**Street address**

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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*