

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of adding B vitamins to diclofenac on the pain after cesarean section

#### Protocol summary

##### Summary

A randomized, single blinded clinical trial with the aim of determining the effect of adding vitamins B to diclofenac on postoperative pain after elective cesarean section 110 from eligible pregnant women undergoing elective cesarean section surgery in Ayatola Taleghani Hospital in Ilam in 1396 Done. In this study, sampling was done first in an unpredictable way, then the units were randomly assigned to diclofenac and diclofenac + B group vitamins. . Inclusion criteria: age 18-35, single-pregnancy, lack of history of high blood pressure, no previous underlying disease, such as heart disease, liver, kidney and seizure, mass index <30 and weight more than 50 kg. Exclusion criteria: placenta previa, placenta abruption, poly hyderamenyaos, need for opiate in recovery, longer surgery, and more general anesthesia. In both groups, the severity of the pain was first measured after surgery and entering the department with the onset of pain, then diclofenac in the group (1) and diclofenac and norobion injected intramuscularly in group (2). Then, the severity of pain and complications after surgery, such as nausea, vomiting, dizziness and ... are recorded at 1, 2, 4, 6, 8, and 12 hours. Diclofenac and pethidine levels are recorded in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201711126790N7**  
Registration date: **2017-11-20, 1396/08/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-11-20, 1396/08/29

#### 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

Deputy of Research and Technology of Ilam University of Medical Sciences

#### Expected recruitment start date

2017-11-16, 1396/08/25

#### Expected recruitment end date

2018-01-15, 1396/10/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of adding B vitamins to diclofenac on the pain after cesarean section

#### Public title

The effect of adding B vitamins to diclofenac on the cesarean pain

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: age 18-35, single-pregnancy, lack of history of high blood pressure, no previous disease, such as heart disease, liver, kidney and seizure, mass index

<30 and weight more than 50 kg. . Exclusion criteria: placenta previa, placenta abruption, polyhydramenyaos, need for opiate in recovery, longer surgery, and more general anesthesia

#### Age

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

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **110**

#### 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 Ethics committee

##### Street address

Ilam University of Medical Sciences

##### City

Ilam-Banganjab

##### Postal code

6939177143

#### Approval date

2017-05-10, 1396/02/20

#### Ethics committee reference number

ir.medilam.rec.1396.18

## Health conditions studied

### 1

#### Description of health condition studied

postoperative pain after cesarean section

#### ICD-10 code

082-9

#### ICD-10 code description

Delivery by caesarean section, unspecified

## Primary outcomes

### 1

#### Description

severity of pain

#### Timepoint

1, 2, 4, 6, 8, and 12 hours after cesarian

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

complications after surgery

#### Timepoint

1, 2, 4, 6, 8, and 12 hours after cesarian

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

In the control group, diclofenac injections are injected intramuscularly.

#### Category

Treatment - Drugs

### 2

#### Description

In the intervention group, diclofenac and neurobion are injected intramuscularly

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatola Taleghani Hospital

##### Full name of responsible person

zainab suhrabi

##### Street address

Ilam beside to Iran Khodro

##### City

Ilam

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ilam University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Kalvandi - Deputy of Research and Technology of the University

**Street address**

Banganjab - Deputy of Research and Technology University

**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**

Master of Midwifery Education / Midwifery Manager

**Other areas of specialty/work****Street address**

Banganjab- pajohesh Blvd- Faculty of Nursing and Midwifery

**City**

Ilam

**Postal code**

00988412227123

**Phone**

+98 84 3222 7123

**Fax****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**

Master of Midwifery Education

**Other areas of specialty/work****Street address**

Banganjab- pajohesh Blvd- Faculty of Nursing and Midwifery

**City**

Ilam

**Postal code**

00988412227123

**Phone**

+98 84 3222 7123

**Fax****Email**

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**

Master of Midwifery / Midwifery Manager

**Other areas of specialty/work****Street address**

ترجمه ایلام- بانگنجا- بلوار پژوهش- دانشکده پرستاری و مامایی  
54/5000 Elam-Banganjab- pajohesh Blvd- Faculty of Nursing and Midwifery

**City**

Ilam

**Postal code**

00988412227123

**Phone**

+98 84 3222 7123

**Fax****Email**

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

**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*