

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