

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

not Blind Comparison of analgesic effect of pethedin, diclophenac and morphin after caesarean section in pregnant females came to ValiAsr Hospital of Birjand according to Visual analog Scoring (VAS)

Protocol summary

Summary

Objectives: comparison of analgesic effect of pethedin, diclophenac and morphin after cesarean section Design: randomized, not blinded, placebo used, single center, phase 1 trial (not available) Setting and conduct: according to Include&exclude criteria the population selected and get Informed consent for this study. The Patient won't be informed about type of drug they will get. not blindly all population divided into 3 groups for pain control with different drugs, in each group pain control will be compared with each other group. Members of Research team member won't be informed about the drug used for patients. Participants including major eligibility criteria: pregnant females candidates for cesarean section for delivery. include criteria: 1- Elective cesarean section 2- primy gravid or not complicated cesarean section 3- No Medical condition in Mother 4- using Spinal analgesia for cesarean section exclusion criteria: 1- history of Medical Condition 2- history of twin pregnancy 3- pethedin hypersensitivity 4- opiom addiction 5- Blood Pressure lower than 90/60 or higher than 180/110 6- history of psychologic disorders Interventions: we are going to intervene on pain relief drugs used after cesarean section, so we use one of drugs (Morphin, Pethedin and Diclofenac) for each one of groups Main Outcomes: 1- pain immediately after cesarean section 2- pain 1 hour after cesarean section 3- pain 12 hour after cesarean section 4- pain 24 hour after cesarean section

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082618934N1**
Registration date: **2014-11-10, 1393/08/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-10, 1393/08/19

Registrant information

Name

Seyed hamid Hoseini

Name of organization / entity

Birjand University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 3041

Email address

hamid_hoseini@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

not Blind Comparison of analgesic effect of pethedin, diclophenac and morphin after caesarean section in pregnant females came to ValiAsr Hospital of Birjand according to Visual analog Scoring (VAS)

Public title

Comparison of analgesic effect of pethedin, diclophenac and morphin after caesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Elective caesarean section; primy gravid or not complicated caesarean section; No Medical condition in Mother (cardiac, respiratory, hepatic or neurologic); using Spinal analgesia for caesarean section; Exclusion criteria: history of Medical Condition such as Renal disorders, hypertension during pregnancy, active peptic ulcer, laparostomy, cardiac diseases; history of twin pregnancy; pethedin hypersensitivity; opiom addiction; Blood Pressure lower than 90/60 or higher than 180/110; history of psychologic disorders like Pain Disorders, Sommatization Disorder, and histyric Personality

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In the pethedin and morphin groups, a placebo Suppository will be used as placebo. In the diclophenac group, a Dextrose Water 5% injection will be used as placebo. Period and amount of prescription will be similar in all groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Birjand University of Medical science

Street address

Ghafaari ave., Birjand

City

Birjand

Postal code**Approval date**

2014-09-06, 1393/06/15

Ethics committee reference number

1393-06-04

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

pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

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

Pain immediatly after cesarean section

Timepoint

limmediatly after cesarean section

Method of measurement

Visual analog Scoring

2**Description**

Pain 1 hour after cesarean section

Timepoint

1 hour after cesarean section

Method of measurement

Visual analog Scoring

3**Description**

Pain 12 hour after cesarean section

Timepoint

12 hour after cesarean section

Method of measurement

Visual analog Scoring

4**Description**

Pain 24 hour after cesarean section

Timepoint

24 hour after cesarean section

Method of measurement

معیار آنالوگ بینایی

Secondary outcomes

empty

Intervention groups

1

Description

Use Pethedine as analgesic 50 miligram/kilogram Intera muscular three times a day

Category

Treatment - Drugs

2

Description

Use Morphine as analgesic 10 miligram/kilogram Intera rectal three times a day

Category

Treatment - Drugs

3

Description

Use Diclofenac as analgesic 50 miligram/kilogram Intera rectal three times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Department of Valiasr Hospital of Birjand

Full name of responsible person

Ghanbarzadeh N. MD

Street address

Vali Asr Hospital, Ghafari ave., Birjand

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Zarban Dr.

Street address

Birjand University of Medical science, Ghafaari ave., Birjand

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Birjand 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

Birjand University of Medical science

Full name of responsible person

Ghanbarzadeh N. MD

Position

Gynecologist/ head of Gynecology Department of Birjand University of Medical science

Other areas of specialty/work

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Science

Full name of responsible person

Hosseyni S.H.

Position

Medical Student (Intern)

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

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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