Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effects of ketorolac and pethidine on pain control and duration of analgesia after cesarean section

Protocol summary

Summary

This double-blind study aims to compare the effects of ketorolac and pethidine on pain intensity and duration of analgesia after cesarean section. A total of 102 candidates for elective caesarean section admitted to Vali-asr Hospital of Birjand will participate if they will to participate and have inclusion criteria (lack of dependency on opioids, atopy and bronchial asthma, diabetes, renal and hepatic disease, alcohol or drugs abuse, gestational hypertension, preeclampsia and peptic ulcer disease, multiple pregnancy, obesity, infant macrosomia). They will be randomly allocated into two intervention groups (n=61 per group) using simple random sampling method. One group will receive ketorolac (30 mg for those <50 kg; 60mg for those >50 kg) and the second group would have pethidine (30 mg). After 4 hours, Faces Pain Scale and Visual Analog Scale will be used to measure pain. The patients will not receive any tranquilizer during the 4 hours but 20 mg of pethidine in case of severe pain. Analgesia duration will be acknowledged by the patients during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101317756N8**
Registration date: **2016-10-17, 1395/07/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-17, 1395/07/26

Registrant information

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Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research, Birjand University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of ketorolac and pethidine on pain control and duration of analgesia after cesarean section

Public title

Effects of ketorolac and pethidine on pain control and duration of analgesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Candidates for elective caesarean section willing to participate; lack of dependency on opioids, atopy and bronchial asthma, diabetes, renal and hepatic disease, alcohol or drugs abuse, gestational hypertension, preeclampsia and peptic ulcer disease,

multiple pregnancy, obesity, infant macrosomia; exclusion criteria: unwillingness to continue participation.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Vice-Chancellery of Research, Birjand University of Medical Sciences, Ghaffari St.,

City
Birjand,

Postal code

Approval date
2015-12-21, 1394/09/30

Ethics committee reference number
Ir.bums.1394.60

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.9

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain intensity

Timepoint
4 hours after treatment

Method of measurement
Faces Pain Scale and Visual Analog Scale (VAS)

2

Description
Anelgesic duration

Timepoint
From end of intervention until first pain onset

Method of measurement
patient self-report

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group (i.e., The Ketorolac group): Having undergone general anesthesia, they will get injected by Ketorolac (30 mg for those <50 kg; 60 mg for those >50 kg). After 4 hours, Faces Pain Scale and Visual Analog Scale will be used to measure pain. The patients will not receive any tranquilizer during the 4 hours but 20 mg of pethidine in case of severe pain. Analgesia duration will be recorded upon the patients' acknowledgement.

Category
Treatment - Drugs

2

Description
The second intervention group (i.e., The Pethadine group): Having undergone general anesthesia, they will get injected by Pethidine (30 mg). After 4 hours, Faces Pain Scale and Visual Analog Scale will be used to measure pain. The patients will not receive any tranquilizer during the 4 hours but 20 mg of pethidine in case of severe pain. Analgesia duration will be recorded upon the patients' acknowledgement.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-Asr Hospital

Full name of responsible person
Zeinab Abbaspour Benhangi

Street address

Ghaffari St.,
City
Birjand,

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellery for Reasearch at Birjand University of Medicla Sciences
Full name of responsible person
Dr Tooba Kazemi
Street address
Ghaffari St.,
City
Birjand,
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellery for Reasearch at Birjand University of Medicla 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

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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