

# 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

##### Name

Mohammad Bagher Roozgar

##### Name of organization / entity

Birjand University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

mbroozgar@bums.ac.ir

##### 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

lr.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

#### Contact

**Name of organization / entity**  
Birjand Univercity of Medical Sciences

**Full name of responsible person**  
Zainab Abbaspour Benhangi

**Position**  
Student of Medicine

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

#### Contact

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Assistant Professor in Anesthesia

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## Person responsible for updating data

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PhD Candidate in Translation Studies

**Other areas of specialty/work**

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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*