Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The comparison between high dose suppository Diclofenac and Pethidine in post cesarean section pain relief

Protocol summary

Study aim
The comparison of suppository Diclofenac and Pethidine in post C-section pain relief in Kamali Hospital

Design
Clinical trial with control group, three parallel groups, double blind, randomized, phase 2 on 90 patients. The rand function of Excel software was used for randomization.

Settings and conduct
90 patients of Kamali Karaj Hospital with separate indications for c-section will be divided into three groups: 100mg diclofenac suppository, 200mg diclofenac suppository and 1mg/kg pethidine intramuscular injection. Then the patients will be examined in terms of pain intensity, average duration until pain relief and other side effects including postpartum bleeding.

Participants/Inclusion and exclusion criteria
Inclusion: pregnant women who have a full-term fetus of 37 weeks or more, aside C-section indication, aged between 18 and 45 Exclusion: Allergy to NSAID and pethidine, history of bronchial asthma, drug addiction, abuse of alcohol, opium or any drug that impairs the perception of pain, proctitis, coagulation disorder, ulcers of the gastrointestinal tract, either a gastric ulcer or History of gastrointestinal bleeding, long-term steroid treatment or continuous use of analgesics, neurological or psychological disorders, users of drugs that interact with pethidine, including MAO inhibitors (such as isocarboxazid, methylene blue, linezolid, pentazocine, nalbuphine, butorphanol, carbamazepine, phenytoin, etc.), liver and kidney diseases

Intervention groups
Patients will be randomly divided into 3 groups through the random numbers table. Immediately after surgery, the first group will be prescribed 100 mg of diclofenac suppository, the second group will be prescribed 200 mg of diclofenac suppository, and the third group will be prescribed 1mg/kg of pethidine intramuscular injection.

Main outcome variables
Post C-section pain, bleeding, drowsiness, hypotension, and respiratory disorders

General information

Reason for update

Acronym
DPK

IRCT registration information
IRCT registration number: **IRCT20220903055861N1**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date
2023-06-06, 1402/03/16

Registrant information

Name
Elham oliaei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 4437 7402

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elhamoliaei70@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between high dose suppository Diclofenac and Pethidine in post cesarean section pain relief

Public title

The comparison between high dose suppository Diclofenac and Pethidine in post cesarean section pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Full-term Pregnant women Aside C-section indication Full-term alive neonate Age between 18 and 45 year Participation consent

Exclusion criteria:

Patients who show an allergic reaction to the drug will be excluded from the study History of allergy to NSAID and pethidine Bronchial asthma Drug addiction, alcohol abuse, opium addict or the use of any drug that impairs the perception of pain Proctitis Coagulopathy Gastrointestinal tract ulcers, stomach ulcers, history of gastrointestinal bleeding Long-term steroid treatment or continuous use of painkillers Neurological or psychological disorders Users of medications that interact with pethidine, such as MAO inhibitors (e.g., isocarboxazid , methylene blue, linezolid), certain pain medications (e.g., pentazocine, nalbuphine, butorphanol), seizure medications (e.g., carbamazepine, phenytoin) Liver and kidney diseases

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the block randomization method will be used to reach the same sample size in all 3 groups. In order to hide the allocation of unequal size blocks, it will be considered in the form of 3, 6, and 9 blocks. The randomization list will be provided using the web-based software provided at the following URL. https://www.sealedenvelope.com/simple-randomiser/v1/lists There is no possibility of blinding the patient, but the researcher evaluating the results and the data analyst will not be informed about the assigned groups.

Blinding (investigator's opinion)

Not 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 Alborz University of Medical Sciences

Street address

Kamali hospital, Kamali alley, Shahid-Beheshti Blvd

City

Karaj

Province

Alborz

Postal code

3134877179

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.ABZUMS.REC.1402.040

Health conditions studied

1

Description of health condition studied

Post C-section pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient's pain according to visual measurement criteria

Timepoint

2 and 6 hour after C-section

Method of measurement

Visual measurement criteria

Secondary outcomes

1

Description

Drowsiness

Timepoint

2 and 6 hour after C-section

Method of measurement

Glasgow Coma Scale

2

Description
Hypotension
Timepoint
2 and 6 hour after C-section
Method of measurement
Sphygmomanometer

3

Description
Abnormal bleeding
Timepoint
2 and 6 hour after C-section
Method of measurement
Physical exam

4

Description
Respiratory disfunction
Timepoint
2 and 6 hour after C-section
Method of measurement
Spirometry and clinical examination

Intervention groups

1

Description
Intervention group: 200 mg diclofenac suppository
Category
Treatment - Drugs

2

Description
Intervention group: Intramuscular injection pethidine g/mg1
Category
Treatment - Drugs

3

Description
Control group: 100 mg diclofenac suppository
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Karaj Kamali Hospital
Full name of responsible person
Elham sadat Oliaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Alborz University of Medical Sciences
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Elham sadat Oliaei
Position
medical student
Latest degree
Medical doctor
Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Information about the main outcome can be shared after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
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From where data/document is obtainable
Dr. Elham Sadat Oliaei Elhamoliaei70@gmail.com

What processes are involved for a request to access data/document
After receiving the email from the applicants and approval by Alborz University of Medical Sciences, information will be sent within 6 months

Comments