Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Preemptive Effect of Gabapentine and Intra techal Fentanyl on Post operative Pain after Caesarean Surgery.

Protocol summary

Summary

In double blind randomized clinical trail, 60 patients candidate for elective caesarian with ASA I –II who accepted to come to study divide to equals group(n=30). All the patients in control group receive 15 micrograms of fentany plus bupiuvacaine .05% up to 2 milliliter. Fentany is a synthetic opioid with receptor in CNS. In case group all the patients receive 300 milligrams gabapentin 2 hours before surgery and receive bupiuvacaine .05% up to 2 milliliter intratechaly before surgery. Gabapentin is gaba amino butyric acid inhibitor and can reduce post operative pain. Pain score, need to analgesic drugs, patient satisfaction, neonate apgar and time of discharge, will be recorded and analyzed in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202241936N8**
Registration date: **2012-03-01, 1390/12/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Science

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Preemptive Effect of Gabapentine and Intra techal Fentanyl on Post operative Pain after Caesarean Surgery.

Public title

Comparison of Preemptive Effect of Gabapentine and Intra techal Fentanyl on Post operative Pain after Caesarean Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the entire patient candidates for elective cesarean age between 20 till 40 that accept to come to study are inclusion criteria. Exclusion criteria: history of sensitivity to gabapentin; patient with hepatic and renal problem; history of epilepsy; patients that received analgesic 8 hours before surgery; patients with psychological problem; history of sensitivity to opioids and any situation that made regional anesthesia contraindicated.

Age

From **20 years** old to **40 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Bushehr university of medical science
Street address
Bushehr-SIRAF AVENUE
City
Bushehr
Postal code
Approval date
2012-02-08, 1390/11/19
Ethics committee reference number
B-90-13-9

Health conditions studied

1

Description of health condition studied
Post operative pain
ICD-10 code
O74.9
ICD-10 code description
Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description
Post operative pain
Timepoint
First 24 hours
Method of measurement
Observation

2

Description
Analgesic demands
Timepoint
First 24 hours
Method of measurement
Observation

Secondary outcomes

1

Description
Patients' statisfication
Timepoint
First 24 hours
Method of measurement
Question

Intervention groups

1

Description
In case group all the patients receive spinal anesthesia with bupiuvacaine .05% up to 2 milliliter.in this group all the patients receive 300 milligrams gabapentin orally 2 hours before surgery as preemptive analgesic protocol.
Category
Treatment - Drugs

2

Description
All the patient in control group receive 15 micrograms of fentany as pain protocol plus bupiuvacaine .05% up to 2 milliliter intratechaly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bentolhoda hospital
Full name of responsible person
Street address
City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr majid asady
Street address
Bushehr University of Medical Sciences
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr 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
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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