Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparision of the effect of oral Gabapentin compare to intravenous Dexamethasone on postoperative pain after elective hysterectomy

Protocol summary

Study aim
Determining the effect of oral gabapentin compared to intravenous dexamethasone as a prodrug on postoperative pain after hysterectomy

Design
Placebo drugs will be prepared by the Faculty of Pharmacy in nameless and colorless packages. Pain intensity will be recorded at 0 (recovery), 2, 6, 12, and 24 hours after surgery based on the Visual Analogue Scale (VAS). Also, in the first 24 hours after the operation, whenever the patient has pain with a VAS greater than 4, they will receive diclofenac suppositories 100 mg.

Settings and conduct
Ayatollah Mousavi Zanjan Hospital

Participants/Inclusion and exclusion criteria
In this study, 93 patients aged 30 to 65 years and ASA (American Society of Anesthesiologists) class one or two, candidates for elective abdominal hysterectomy, referred to Ayatollah Mousavi Hospital in Zanjan will be included in the study.

Intervention groups
Patients are divided into three groups using block randomization. The first group was given 600 mg of oral gabapentin and intravenous placebo half an hour before surgery, the second surgery group was prescribed 8 mg of intravenous dexamethasone and oral placebo, and the third group or the control group will receive both oral placebo and intravenous placebo.

Main outcome variables
Information related to the time of requesting the first dose of painkillers, the amount and frequency of painkiller requests in the first 24 hours after the operation, the frequency of nausea and vomiting, and dizziness are recorded in the file.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200421047160N2**
Registration date: **2023-05-07, 1402/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-07, 1402/02/17**
Update count: **0**

Registration date
2023-05-07, 1402/02/17

Registrant information

Name
Azadeh Hosseinkhani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparision of the effect of oral Gabapentin compare to intravenous Dexamethasone on postoperative pain after elective hysterectomy

Public title
The effect of oral Gabapentin and intravenous Dexamethasone on postoperative pain after hysterectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient consent to participate in the study ASA class 1 or 2 Candidate for non-emergency abdominal hysterectomy surgery Hysterectomy for non-malignant reasons Lack of sensitivity to Gabapentin and Corticosteroids No history of chronic pain and neurological diseases Not receiving any kind of pain medication in the last 24 hours Not having diabetes and Hypertention
Exclusion criteria:
Extending the duration of hysterectomy more than 3 hours Occurrence of any unusual complications during surgery Receiving pain medication during the operation
Age
From **30 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization will be used to allocate samples to intervention groups. In this method, blocks of 3 sizes are created, then so many blocks are selected to reach the required sample size in each group. Finally, 31 blocks of 3 will be created.
Blinding (investigator's opinion)
Double blinded
Blinding description
The outcome assessor, who is a member of another department's staff, is unaware of the type of medication the patient received. Also, the statistical analyzer is not aware of the type of medicine received by the patient and all the samples have a code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Sciences
Street address
Dr. Youssef Tashtobi Blvd, Zanjan University of Medical Sciences
City
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Province
Zanjan
Postal code
4513956184
Approval date
2023-02-12, 1401/11/23
Ethics committee reference number
IR.ZUMS.REC.1401.331

Health conditions studied

1

Description of health condition studied
Pain intensity after hysterectomy surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain score after hysterectomy
Timepoint
in hours 0 (recovery), 2, 6, 12, 24 after the operation
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Determining the need for additional painkillers
Timepoint
in hours 0 (recovery), 1, 6, 12, and 24 hours after hysterectomy
Method of measurement
Patient request and registration in the medical record

2

Description
The rate of side effects (nausea and vomiting, confusion and drowsiness, palpitations)
Timepoint
in hours 0 (recovery), 1, 6, 12, and 24 hours after hysterectomy
Method of measurement
registration in the medical record

Intervention groups

1

Description
Intervention group: Half an hour before the start of surgery, 600 mg of oral gabapentin and intravenous placebo
Category
Treatment - Drugs

2

Description
Intervention group: Half an hour before surgery, 8 mg of intravenous dexamethasone and oral placebo
Category
Treatment - Drugs

3

Description
Control group: Half an hour before the surgery, both oral placebo and intravenous placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Zanjan Hospital
Full name of responsible person
Neda Zamanpour
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Sponsors / Funding sources

1

Sponsor
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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
Zanjan 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
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Azadeh Hosseinkhani
Position
instructor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable