

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 Zanzan 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 Zanzan 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

Country

Iran (Islamic Republic of)

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+98 24 3336 2447

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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

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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 Zanjani Hospital

Full name of responsible person

Neda Zamanpour

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Ayatollah Mousavi Hospital, Professor Tasbati Blvd., Zanzan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Azadeh Hosseinkhani

Position

instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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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

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Azadeh Hosseinkhani

Position

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