

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the preoperative analgesia effects of oral Magnesium oxide and Naproxen for hysterectomy surgery in Afzalipour hospital , Kerman, 2019

Protocol summary

Study aim

Comparing the preemptive analgesia effects of oral magnesium oxide and naproxen for hysterectomy surgery in Afzalipour Hospital , Kerman ,Year 1398

Design

A concealed, triple blinded, randomized (random sequence numbers) clinical trial with two arm parallel group (32 patients in each group)

Settings and conduct

This study was conducted among patients candidate hysterectomy in Afzalipour hospital, Kerman. patients received magnesium oxide and naproxen before operation and non of participants, main investigator and data analyser did know the patients allocation (triple blinded)

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of sensitivity to magnesium and naproxen; lack of liver diseases; no lactation
Exclusion criteria: drug or opiod addiction; concomitant treatment with analgesic or anti-inflammatory drugs

Intervention groups

Patients in intervention group received a magnesium oxide tablet (500 mg) and patients in control group received naproxen tablet (500 mg) before operation.

Main outcome variables

Pain score; Pulse rate changes; Blood pressure changes;
Time between end of operation and first prescription of analgesic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044559N1**
Registration date: **2019-11-04, 1398/08/13**
Registration timing: **retrospective**

Last update: **2019-11-04, 1398/08/13**

Update count: **0**

Registration date

2019-11-04, 1398/08/13

Registrant information

Name

Morteza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-13, 1398/05/22

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-08-13, 1398/05/22

Actual recruitment end date

2019-10-14, 1398/07/22

Trial completion date

2019-10-14, 1398/07/22

Scientific title

Comparing the preoperative analgesia effects of oral Magnesium oxide and Naproxen for hysterectomy surgery in Afzalipour hospital , Kerman, 2019

Public title

Effect of oral Magnesium oxide on preoperative analgesia in hysterectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
No history of sensitivity to magnesium and naproxen
Lack of liver diseases No kidney or cardiovascular dysfunction no lactation age between 35 to 65

Exclusion criteria:
drug or opiod addiction neurological disorder, pain or abuse of opiod analgesic Concomitant treatment with analgesics or anti-inflammatory drugs Chronic treatment with magnesium or calcium channel blockers Patients with complicated appendectomy

Age
From **35 years** old to **65 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients randomly divided in two groups (32 patients in each group) using random allocation sequence with SAS statistical software. according to this method a simple randomization list product and patients` involvement in each group determine base on order entry. we used sequentially numbered, sealed opaque envelopes for allocation concealment. patients (individuals) were the randomization units.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients, main investigator and data analyser were masked of patients allocation. patients did not know which drug prescribed and checklists did not contain any drug name. only the nurse know the name of medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical

Sciences

Street address
Vice-challenger of Research, Ebn-e sina St., Jahad blvd.

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2019-09-02, 1398/06/11

Ethics committee reference number
IR.KMU.AH.REC.1398.081

Health conditions studied

1

Description of health condition studied

Pain after hysterectomy surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain score after hysterectomy surgery

Timepoint

After surgery and consciousness of the patient

Method of measurement

VAS scale

2

Description

Pulse rate changes

Timepoint

During operation

Method of measurement

Arm cuff

3

Description

Blood pressure changes

Timepoint

During operation

Method of measurement

Arm cuff

4

Description

Time between end of operation and first prescription of analgesics

Timepoint

The first time that patient need analgesic

Method of measurement

patient demand

Secondary outcomes**1****Description**

Chill feeling

Timepoint

After operation

Method of measurement

Clinical symptoms

2**Description**

Nausea

Timepoint

After operation

Method of measurement

Clinical symptoms

3**Description**

Vomiting

Timepoint

After operation

Method of measurement

Clinical symptoms

Intervention groups**1****Description**

Intervention group: receiving oral Magnesium oxide (500 mg) 1.5 hour before surgery

Category

Prevention

2**Description**

Control group: receiving oral Naproxen (500 mg) 1.5 hour before surgery

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Afzalipour hospital

Full name of responsible person

Morteza Hashemian

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Afzalipour hospital, Imam khomeini Highway

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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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

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Morteza Hashemian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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