

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparative study of effect of second dose of pregabalin, acetaminophen, naproxen and dextromethorphan on postoperative analgesia

Protocol summary

Study aim

Determination and comparison of the effect of the second dose of the combination of Pregabalin, Acetaminophen, Naproxen and Dextromethorphan on postoperative analgesia

Design

Randomized, double blinded, sham controlled clinical trial 60 Patients are divided into two groups randomly according to the random number table to receive the second dose of agents after transferred to the ward; A group that has an individual number receives a second dose of the non-narcotic drugs combination and the other group (paired numbers) receives the placebo.

Settings and conduct

Evaluation of the severity and type of pain after surgeries: Nephrectomy, Cystectomy, Prostatectomy, Colectomy, Vippel and RPLND in Imam Khomeini Hospital in intervention group (administration of the second dose of non-narcotic drugs combination) and control group (placebo) The drug combination and the placebo will be packed in the same white envelopes as the research guide and will be provided to the prescribes for the second dose

Participants/Inclusion and exclusion criteria

Including criteria: All patients with ASA-PS score of one to three who are on the list of surgeries: Nephrectomy, Cystectomy, Prostatectomy, Colectomy, Vippel and RPLND and aged 18 to 80 years Excluding criteria: Drug addicts History of taking antidepressants and anticonvulsants in the last 6 months Any contraindication or allergy to Pregabalin, Acetaminophen, Naproxen and Dextromethorphan Patients who are not extubated after surgery

Intervention groups

Within 6 hours after Discharge from the recovery, In the intervention group the second dose of PAND is repeated And in the control group placebo is prescribed.

Main outcome variables

Age; Sex; surgery Indication; Type of surgery; Patient's group; Time of first opioid request; Sum of opioid received; Pain intensity; Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181219042046N1**
Registration date: **2019-04-19, 1398/01/30**
Registration timing: **prospective**

Last update: **2019-04-19, 1398/01/30**

Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

Majid Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3441 5047

Email address

aminimajid1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of effect of second dose of pregabalin, acetaminophen, naproxen and dextromethorphan on postoperative analgesia

Public title
Effect of non-narcotic agents on postoperative analgesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with ASA-PS score of one to three who are on the list of surgeries: Nephrectomy, Cystectomy, Prostatectomy, Colectomy, Vippel and RPLND and aged 18 to 80 years
Exclusion criteria:
Drug addicts Any contraindication and allergy to Pregabalin, Acetaminophen, Naproxen and Dextromethorphan Patients who are not extubated after surgery

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups randomly according to the random number table to receive the second dose after being transferred to the ward; Accordingly, each patient is assigned a random number (individual or paired) randomly. The combination of the drug and the placebo will be packed in the same white envelopes as the research guide and will be provided to the prescribes for the second dose. A group that has an individual number receives a second dose of the drug compound and the other group (paired numbers) receives the placebo. The only person who knows the contents of the envelope is the research guide and the patients, the administrators and outcome evaluator are unaware.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug combination and the placebo will be packed in the same white envelopes as the research guide and will be provided to the prescribes for the second dose.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Imam Khomani Hospital Complex, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417933791

Approval date
2018-04-18, 1397/01/29

Ethics committee reference number
IR.TUMS.IKHC.REC.1398.017

Health conditions studied

1

Description of health condition studied
Postoperative pain

ICD-10 code
T40.0

ICD-10 code description
Poisoning by, adverse effect of and underdosing of opium

Primary outcomes

1

Description
Pain severity by using UPAT (universal pain assessment tool)

Timepoint
Pain measurement at 0, 2, 4, 6, 8, 12, 24, 48 hours after surgery

Method of measurement
UPAT (universal pain assessment tool)

Secondary outcomes

1

Description
29/5000Type of pain: somatic or neuropathic

Timepoint

Evaluation at times 0, 2, 4, 6, 8, 12, 24 and 48 hours after surgery

Method of measurement

Descriptive history of the patient

Intervention groups

1

Description

Intervention group: Administration of the second dose of the combination of Cap Pregabalin 300mg, Tab Acetaminophen 1g, Tab Naproxen 500mg and Tab Dextromethorphan 30 mg for postoperative analgesia

Category

Treatment - Drugs

2

Description

Control group: Prescribing a placebo instead of a second dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomaini Hospital Complex

Full name of responsible person

Majid Amini

Street address

Imam Khomaini Hospital Complex, Keshavarz Blvd.,
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aminimajid1990@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeyan

Street address

Imam khomeini Hospital Complex- Keshavarz Blvd -
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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Tehran University of Medical Sciences

Full name of responsible person

Majid Amini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Resident

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

severity and type pain

When the data will become available and for how long

6 month after outcomes released

To whom data/document is available

academic and scientific persons

Under which criteria data/document could be used

There is no limit to the use of data or documentation due to unidentifiable patient information.

From where data/document is obtainable

Majid Amini aminimajid1990@gmail.com

What processes are involved for a request to access data/document

After receiving an application via email, it will be answered for one week.

Comments