Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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, Cystetomy, 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, Cystetomy, 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, Cystetomy, 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 Khomaini 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., Tehran, Iran
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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 - Tehran - Iran
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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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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