

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation of the effectiveness of preemptive analgesia in combination of Pregabalin, Acetaminophen, Naproxin, Dextrometorhan in Radical neck dissection in Cancer institute of Imam khomeini Hospital

Protocol summary

Summary

A double blind randomized clinical trial, in head and neck surgeries, has been designed to evaluate the preemptive analgesia efficacy of combination of Pregabalin, Naproxin, Acetaminophen and Dextrometorphan to reduce the post operative pain and opioid consumption. Inclusion criteria: patients aged 18-60 years old; ASAps I; candidated for radical neck dissection surgery. Exclusion criteria: history of addiction; ASAps II and more; A drug history of anti convulsant and anti depression; history of gastrointestinal problem and chronic neck pain before surgery. Method: Patients had been divided in two groups, each 40 randomly by age, sex and weight. The case group recieved the combination of Pregabalin, Naproxin, Acetaminophen, dextrometorphan orally, 1 hour before surgery, which dosage according to the weight. For all patients in both groups, the same anesthetic procdure has been used. After finishing the surgery, when the patients has been transfered to recovery then surgery ward, the pain score, the firt time that patients need analgesia and the total dose of morphine in 24 hours has been evaluated and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011620676N1**
Registration date: **2016-03-19, 1394/12/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-19, 1394/12/29

Registrant information

Name

Farhad Tavakoli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of preemptive analgesia in combination of Pregabalin, Acetaminophen, Naproxin, Dextrometorhan in Radical neck dissection in Cancer institute of Imam khomeini Hospital

Public title

Evaluation of the effectiveness of preemptive analgesia in Combination of Pregabalin, Acetaminophen, Naproxin, Dextrometorhan in Radical neck dissection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18-60 years old; ASAs I; candidated for radical neck dissection surgery. Exclusion criteria: ASAs II and more; History of addiction; Drug history for: anti convulsant, anti depression; History of gastrointestinal problem; chronic neck pain before surgery.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

6th floor, Tehran University of Medical Sciences,
Ghods st. Keshavarz blvd.

City

Tehran

Postal code

Approval date

2014-11-25, 1393/09/04

Ethics committee reference number

130/2171/93/ص

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain score

Timepoint

At the interance to ward and after 2, 4, 6, 8, 12, 24 hours

Method of measurement

Universal Pain Assessment Tools (UPAT)

Secondary outcomes

1

Description

Total dose of morphine during 24 hours

Timepoint

At the end of 24 hours

Method of measurement

Patient's medical records

Intervention groups

1

Description

to interventional group: pregabalin (2.5 mg/kg)
dextrometorphan (0.3 mg/kg) Naproxin(7mg/kg),
acetaminophen (15mg/kg) orally 1 hour before surgery.

Category

Prevention

2

Description

The control group was not received the combination
medicines

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

cancer Institute, Imam Khomeini Hospital

Full name of responsible person

Farhad Tavakoli M.D.

Street address

Operation Rooms of the Cancer Institute Building,
Imam Khomeini Hospital, Keshavarz blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhond zadeh M.D

Street address

Head center , Keshavarz Blv.

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

MD, Anesthesia residency

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty