

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of sedative and analgesic effect of Gabapentin and Dexmedetomidine in patients undergoing laparoscopic surgery

Protocol summary

Summary

The plan of this study is to compare efficacy of sedative and analgesia effect of gabapentin and dexmedetomidine in patients undergoing laparoscopic surgery .the study is pilot randomized and open label (not blinded).the 40 patients undergoing laparoscopic surgery are under study. Entry criterion: Age between 18 and 65 ASA1, 2 Body mass index lower than 28 kg on stature product Acquire written consent Exit criterion: Existence of records in a systemic malady (high blood pressure, ischemic heart, and etc...), allergies records, contraindications of gabapentin and dexmedetomidine Addiction to drugs and alcohol Pregnancy Sample size: 40 patients undergoing laparoscopic surgery Types of interventions: the first group (control group): gabapentin, 300 mg one hour before surgery The second group (intervention group): Group II dexmedetomidine 0.5-1 micrograms per patient weight morning before practice. The primary outcome: anxiety scale measured and checked Ramsay Secondary outcome: pain measured by VAS scale and checked. Intervention time: 9 months

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011822794N2**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Bahador Bagheri

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences - Research and development Vice

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedative and analgesic effect of Gabapentin and Dexmedetomidine in patients undergoing laparoscopic surgery

Public title

Comparison of sedative and analgesic effect of Gabapentin and Dexmedetomidine

Purpose

Treatment

Inclusion/Exclusion criteria

Entry criterion: Age between 18 and 65 ASA1, 2 Body mass index lower than 28 kg on stature product Acquire written consent Exit criterion: Existence of records in a systemic malady (high blood pressure, all types of collagen disease, ischemic heart, kidney, digestive

system and etc...), allergies records, contraindications of gabapentin and dexmedetomidine Addiction to drugs and alcohol Pregnancy Paroxysmal

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences - Research and development Vice

Street address

Semnan University of Medical Sciences

City

Semnan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

1394.142

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06

ICD-10 code description

Other mental disorders due to brain damage and dysfunction and to physical disease

Primary outcomes

1

Description

Anxiety

Timepoint

6 hours after intervention

Method of measurement

Ramsay scale

2

Description

Pain

Timepoint

6 hours after intervention

Method of measurement

standard questionnaires VAS

Secondary outcomes

1

Description

Sleep without provocation

Timepoint

6 hours after intervention

Method of measurement

Ramsay scale

Intervention groups

1

Description

The first group gabapentin, 300 mg one hour before surgery

Category

Treatment - Drugs

2

Description

The second group Dax medetomidine 0.5-1 micrograms per patient weight in the morning before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital in Semnan

Full name of responsible person

Abolfaz IAbdollahpoor

Street address

Kowsar Hospital in Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Semnan University of Medical Sciences

Full name of responsible person

Bahador Bagheri

Street address

Semnan University of Medical Sciences

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Semnan 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

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Abolfazl Abdollahpoor

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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