

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effects of dexmedetomidine and remifentanyl on blood pressure and heart rate in patients undergoing laparoscopic cholecystectomy

Protocol summary

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Summary

The aim of study is prevention or decrease of hemodynamic changes in laparoscopic surgery. If patients have written informed consent ;ASA physical status I and II ;20-65 years old ;BMI less than 30 kg/m² and no opioids addiction , 40 patients scheduled for laparoscopic cholecystectomy with general anaesthesia are divided into two groups to receive infusion of either dexmedetomidine or remifentanyl. uncontrolled hemodynamic changes during surgery and open cholecystectomy are excluded from the study. Blood pressure and heart rate are measured every 5 min and recorded.

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010916151N1**

Registration date: **2014-12-29, 1393/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-29, 1393/10/08

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

Scientific title

Comparison of the effects of dexmedetomidine and remifentanyl on blood pressure and heart rate in patients undergoing laparoscopic cholecystectomy

Public title

Effects of dexmedetomidine on blood pressure and heart rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Written informed consent ;ASA physical status I and II ;20-65 years old ;BMI less than 30 kg/m² ; Patients scheduled for elective laparoscopic cholecystectomy with general anesthesia ;Do not have respiratory disease and cardiac dysfunction and liver disease and renal disease and neuropathology and coagulopathy disease and uncontrolled hypertension ;Do not use of betablocker drugs and psychoactive drugs and analgesic drugs and opioid addiction . Exclusion criteria: uncontrolled hemodynamic changes during surgery;open cholecystectomy

Age

From **20 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)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

Street address

Hemat highway

City

Tehran

Postal code**Approval date**

2014-03-25, 1393/01/05

Ethics committee reference number

92/105/2495/3

Health conditions studied**1****Description of health condition studied**

Heart rate

ICD-10 code

R00

ICD-10 code description

Abnormalities of heart beat

2**Description of health condition studied**

Blood pressure

ICD-10 code

R03

ICD-10 code description

Abnormal blood-pressure reading, without diagnosis

Primary outcomes**1****Description**

Blood pressure

Timepoint

During surgery

Method of measurement

NIBP

2**Description**

Heart rate

Timepoint

During surgery

Method of measurement

ECG

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

Duration of recovery room

Timepoint

Recovery room

Method of measurement

Hour

2**Description**

Degree of pain

Timepoint

Recovery room

Method of measurement

VAS

3**Description**

Nasa and Vomiting

Timepoint

Recovery room

Method of measurement

Observation

4**Description**

Hypotention

Timepoint

During in surgery and recovery room

Method of measurement

NIBP

5**Description**

Bradycardia

Timepoint

During in surgery and recovery room
Method of measurement
ECG

Intervention groups

1

Description

Starting at the anesthesia, patients receive a loading dose of dexmedetomidine 1 micg/kg i.v. administered over 10 min followed by a continuous infusion of 0.7 micg/kg per h.

Category

Treatment - Drugs

2

Description

Starting at the anesthesia, patients receive a loading dose of remifentanyl 1micg/kg i.v. given over 1min followed by a continuous infusion of 0.2 micg/kg/min.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Farahnaz Sadeghi

Street address

Beh-Afarin st.; Karimkhan Zand st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

Iran University of Medical Sciences;Hemat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Firouzgar Hospital

Full name of responsible person

Farahnaz Sadeghi

Position

Resident

Other areas of specialty/work

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Fax

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Web page address

Person responsible for updating data

Contact

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