# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Aug 2026

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

## Protocol summary

**Summary**
The aim of study is prevention or decrease of hemodynamic changes in laparosopic 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 cholesystectomy with general anaesthesia are divided into two groups to recieve infusion of either dexmedetomidine or remifentanile. uncontrolled hemodynamic chenges during surgery and open cholecystectomy are excluded from the study. Blood pressure and heart rate are measured every 5 min and recorded.

## 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 Siences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8894 6762
**Email address**
a-pournajafian@tums.ac.ir

**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

**Scientific title**
Comparison of the effects of dexmedetomidine and remifentanyle 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 coagolopathy disease and uncontrolled hypertention ;Do not use of betablocker drugs and psycoactive drugs and analgesice drugs and opioid adiction . Exclusion criteria: uncontrolled hemodynamic chenges 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/د

## 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**
Bradicardia
**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. administerrd 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 remifentanil 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**

**Street address**

Firouzgar Hospital

**City**

Tehran

**Postal code**

**Phone**

+98 21 8894 6762

**Fax**

**Email**

farahnazsadeghi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Firouzgar Hospital

**Full name of responsible person**

Farahnaz Sadeghi

**Position**

Resident

**Other areas of specialty/work**

**Street address**

Firouzgar Hospital

**City**

Tehran

**Postal code**

**Phone**

+98 21 8894 6762

**Fax**

**Email**

farahnazsadeghi@gmail.com

**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*