

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Analgesic effect of low dose- ketamine during anesthesia induction in 18-80 years pateint under surgery :Strabismus,Retinal Detachment,Keratoplasty**

#### **Protocol summary**

2011-12-15, 1390/09/24

#### **Summary**

This research will be conducted to determine the effect of low dose- ketamine during anaesthesia induction in painful ophthalmic surgery: quantity of intraoperative and postoperative analgesic requirement, postoperative nausea, vomiting and pain. Inclusion criteria:every women and men under surgery of Strabismus,Retinal Detachment,Keratoplasty; have no contraindication of ketamine;have no addiction to drugs;ASAof patient are 1 and2.Exclusion criteria:every women and men under surgery of Strabismus,Retinal Detachment,Keratoplasty less than 18 years and older than 80years;have contraindication of ketamine for exp:increased ICP and IOP.Ischemic heart aneurysms.Psychiatric disease such as schizophrenia.open eye.Target sample size is 88 patients.pateints will be randomly selected that under surgery of Strabismus,Retinal Detachment,Keratoplastyin in Ophthalmology operating room of Esfahan's Fayz hospital in 2010-2011. patients will be randomly divided in 2 groups(case,control).each of the three are equally distributed in 2 groups(case,control). patients of case group during anesthesia induction in addition of anesthtic drugs infuse 0.5mg/kg ketamine intravenous.patients of control group infuse the same volume of saline normal.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201102235889N1**  
Registration date: **2011-12-15, 1390/09/24**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

#### **Registrant information**

##### **Name**

Hasanali Soltani

##### **Name of organization / entity**

Anesthetic and Special Cares Group of Esfahan Medical University

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 1668 5555

##### **Email address**

soltani@med.mui.ac.ir

#### **Recruitment status**

##### **Recruitment complete**

#### **Funding source**

The cost of ketamine that is used in addition to other anesthesia drugs is the responsibility of the researcher

#### **Expected recruitment start date**

2010-12-22, 1389/10/01

#### **Expected recruitment end date**

2011-06-21, 1390/03/31

#### **Actual recruitment start date**

empty

#### **Actual recruitment end date**

empty

#### **Trial completion date**

empty

#### **Scientific title**

Analgesic effect of low dose- ketamine during anesthesia induction in 18-80 years pateint under surgery :Strabismus,Retinal Detachment,Keratoplasty

#### **Public title**

analgesic effect of ketamine in painful ophthalmic surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: every women and men under surgery of Strabismus, Retinal Detachment, Keratoplasty. Exclusion criteria: every women and men under surgery of Strabismus, Retinal Detachment, Keratoplasty less than 18 years and older than 80 years; have contraindication of ketamine for exp: increased ICP and IOP. Ischemic heart aneurysms. Psychiatric disease such as schizophrenia. open eye injury; addict to drugs; ASA of patient are not 1 and 2; any changes in anesthetic plan that cause the use of drugs other than usual; any changes in surgical plan that cause changes in anesthetic plan; any changes in conditions of during surgery that cause changes in anesthesia drugs

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Regional Bioethics Committee in medical reaserches of Medical University of Esfahan

##### Street address

Unit VICE-Chancellory for research and technology, Medical university of Esfahan, Esfahan

##### City

Esfahan

##### Postal code

81745319

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

189066

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

H57.1

#### ICD-10 code description

Ocular pain

### 2

#### Description of health condition studied

Nausea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

Nausea and vomiting

## Primary outcomes

### 1

#### Description

the intensity of pain

#### Timepoint

after the patient's full consciousness in recovery

#### Method of measurement

according on VAS(0-10)

### 2

#### Description

the intensity of nausea

#### Timepoint

after the patient's full consciousness in recovery

#### Method of measurement

according on VAS(0-10)

### 3

#### Description

vomiting frequency

#### Timepoint

in recovery if there is vomiting

#### Method of measurement

counting vomiting frequency in recovery

## Secondary outcomes

### 1

#### Description

maxium of anasthetic drug

#### Timepoint

per 5 minutes until maxium 150microgeram per kg per minutes

#### Method of measurement

microgeram per kg per minutes untill reaching to 80-100% systolic BloodPressure before surgery

## 2

### **Description**

maxuim of analgesic during operation

### **Timepoint**

per 10 minutes

### **Method of measurement**

microgeram per kg untill reaching to 80-100% systolic BloodPressure before surgery

## 3

### **Description**

time interval between end of surgery till extubation

### **Timepoint**

end of surgery till extubation

### **Method of measurement**

Presence of spontaneous breathing of patient with The minimum of normal tidal volume

## 4

### **Description**

analgesic requirement in recovery

### **Timepoint**

after the patient's full consciousness in recovery

### **Method of measurement**

microgeram per kg if VAS=4.bigger than4

## 5

### **Description**

period of time staying in recovery

### **Timepoint**

when paition discharge of recovery

### **Method of measurement**

acourding on patient's conditions of discharge in terms of minutes

## 6

### **Description**

the duration of surgery

### **Timepoint**

time of starting surgery till end of surgery

### **Method of measurement**

in terms of minutes

## 7

### **Description**

mean blood pressure

### **Timepoint**

per 5 min

### **Method of measurement**

in terms of mmhg by blood pressure monitoring device

## 8

### **Description**

pulse

### **Timepoint**

per 5 min

### **Method of measurement**

per minutes by pulse monitoring device

## 9

### **Description**

age

### **Timepoint**

before surgery write in Questionnaire

### **Method of measurement**

years

## 10

### **Description**

sex

### **Timepoint**

before surgery write in Questionnaire

### **Method of measurement**

female-male

## 11

### **Description**

weight

### **Timepoint**

before surgery write in Questionnaire

### **Method of measurement**

kg-by Balance

## 12

### **Description**

Underlying disease

### **Timepoint**

before surgery write in Questionnaire

### **Method of measurement**

Underlying disease:have.not have

## **Intervention groups**

### 1

#### **Description**

Intervention:ketamine,0.5mg/kg during anaesthesia induction received intravenous

#### **Category**

Treatment - Drugs

### 2

#### **Description**

control:normal saline, 0.5mg/kg during anaesthesia induction received intravenous

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Fayz Hospital

**Full name of responsible person**

Mitra Abdollahi,medical student,general physician

**Street address**

Fayz Hospital, Ghods ST., Esfahan

**City**

Esfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

no sponsor

**Full name of responsible person**

no sponsor

**Street address**

Esfahan Medical University

**City**

Esfahan

**Grant name**

-

**Grant code / Reference number**

--

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

Yes

**Title of funding source**

no sponsor

**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**

Islamic Azad Medical University of Najafabad

**Full name of responsible person**

Mitra Abdollahi

**Position**

Medical student-General Physician

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

Islamic Azad Medical University of Najafabad,Najafabad

**City**

Esfahan

**Postal code****Phone**

+98 983312291111

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mitra.abdolahi@Gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Anesthetic and Special Cares Group of Esfahan Medical University

**Full name of responsible person**

Dr. Hasanali Soltani

**Position**

Specialist of Anesthetic and Special Cares

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

Unit of Anesthetic and Special Cares Group of Esfahan Medical University,Basement floor, Alzahra Hospital,Esfahan

**City**

Esfahan

**Postal code****Phone**

+98 31 1668 5555

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**Email**

soltani@med.mui.ac.ir

**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*