

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of propofol with alfentanil and propofol with fentanyl on patient eye movement during cataract surgery under topical anesthesia

Protocol summary

Summary

Objectives: The purpose of this study is to compare the combination of propofol with alfentanil or fentanyl on patient eye movement during cataract surgery under topical anesthesia. **Design:** Two hundreds and forty six patients candidate for cataract surgery. **Setting and conduct:** This is a randomized block, double-blind, without placebo and clinical trial phase II study. **Major inclusion criteria:** patients over the age of 18, candidates for cataract surgery **Major exclusion criteria:** History of cardiovascular and neuromuscular diseases **Interventions:** Patients received 0.3 mg/kg propofol which continued with 0.5 mg/kg/hr propofol. Patients divided in to two groups; group one received intravenous injection of 1 µg/kg fentanyl and in second group patients received intravenous injection of 1 µg/kg alfentanil. **Main outcome measures:** eye movement, heart rate, and arterial blood pressure were recorded at minutes 0, 10, and 30 after onset of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306073289N5**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name

Esmail Moshiri

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

dr_moshiri@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propofol with alfentanil and propofol with fentanyl on patient eye movement during cataract surgery under topical anesthesia

Public title

Different anesthetic methods in reducing patient eye movement during cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patient older than 18 years old

Exclusion criteria: History of cardiovascular disease, History of neuromuscular disorder, History of allergic reaction to anesthetic drugs, history of previous surgery on eye

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample sizeTarget sample size: **246****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**

Ethic committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code**Approval date**

2013-05-12, 1392/02/22

Ethics committee reference number

92-144-6

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

cataract

ICD-10 code

H25

ICD-10 code description

cataract Excluded: capsular glaucoma with pseudo exfoliation of lens

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

Amount of eye movement

Timepoint

At time 0, 10 and 30 after beginning surgery

Method of measurement

quality grading

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

Blood pressure

Timepoint

At time 0, 10 and 30 minutes after beginning surgery.

Method of measurement

Mercury sphygmomanometer according to mmHg

2**Description**

Heart rate

Timepoint

At time 0, 10 and 30 minutes after beginning surgery.

Method of measurement

beat per minute

3**Description**

temperature

Timepoint

At time 0, 10 and 30 minutes after beginning surgery.

Method of measurement

Mercury Termometer

Intervention groups**1****Description**

Propofol 1%, made in Dongkook Pharma. Co. Ltd. South Korea, 0.3 mg/kg that is used in IV injection one time for anesthesia induction

Category

Other

2**Description**

Propofol 1%, made in Dongkook Pharma. Co. Ltd. South Korea, 0.5 mg/kg/hr IV infusion

Category

Other

3**Description**

Intervention 1. Fentanyl (feniject), made in Aburaihan Pharma. Co. Iran, 1 µg/kg IV injection.

Category

Treatment - Drugs

4

Description

Intervention 2. Alfentanil, made in Hameln pharmaceuticals. Co. Ltd. Germany, 1 µg/kg IV injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Dr Esmail Moshiri

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Saeed Changizi Ashtiani

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for Research

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

Arak University of Medical Sciences

Full name of responsible person

Dr Esmail Moshiri

Position

Anesthesiologist, assistant professor

Other areas of specialty/work

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

Arak

Postal code

Phone

+98 86 1223 1104

Fax

Email

dr_moshiri@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Esmail Moshiri

Position

Anesthesiologist, assistant professor

Other areas of specialty/work

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

Arak

Postal code

Phone

+98 86 1223 1104

Fax

Email

dr_moshiri@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Esmail Moshiri

Position

Anesthesiologist, assistant professor

Other areas of specialty/work

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

Arak

Postal code

Phone

00

Fax

Email

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