# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 size**
Target 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 Esmaeil 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 Esmaiel 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 Esmaiel 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 Esmaeil 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*