

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Fentanyl versus Buprenorphine on Pupil Size in Cataract Surgery

Protocol summary

Summary

The aim of this research is to determine the effect of fentanyl (agonist) versus buprenorphine (agonist-antagonist) on pupil size in cataract surgery. All patients who are candidates for cataract surgery under general anaesthesia (GA) could be enrolled into this study. Exclusion criteria: Any situation that makes GA difficult or make pupil size measurement difficult (phaco-emulsification, glaucoma, addiction and history of previous surgery). Sample size is 30 in each group (case and control). The intervention in the case group is injection of buprenorphine 0/3 mcg/kg instead of fentanyl (1mcg/kg). The pupil will be sized pre-induction and 5 minutes after injection of the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008211936N4**

Registration date: **2010-09-11, 1389/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-11, 1389/06/20

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1354 0088

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2010-08-22, 1389/05/31

Expected recruitment end date

2010-10-22, 1389/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fentanyl versus Buprenorphine on Pupil Size in Cataract Surgery

Public title

The Effect of Fentanyl versus Buprenorphine on Pupil Size in Cataract Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients who are candidates for cataract surgery under general anaesthesia (GA) could be enrolled into this study. Exclusion criteria: Any situation that makes GA difficult or make pupil size measurement difficult (phaco-emulsification, glaucoma, addiction and history of previous surgery).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Bushehr University of Medical Sciences

Street address

Siraf avenue

City

Bushehr

Postal code

Approval date

2010-07-01, 1389/04/10

Ethics committee reference number

10578/3/18/20/ب پ

Health conditions studied

1

Description of health condition studied

pupil size response to opioid

ICD-10 code

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ICD-10 code description

Primary outcomes

1

Description

Pupil diameter

Timepoint

Before induction and 5 minutes after induction

Method of measurement

Hand held pupillometer

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

Continuously measured from induction of Anaesthesia till discharge (24 hours)

Method of measurement

questionnaire

2

Description

Shivering

Timepoint

The time at recovery

Method of measurement

observation

3

Description

Discharge from recovery

Timepoint

At the time of discharge

Method of measurement

questionnaire

Intervention groups

1

Description

In control group size of the pupil will be measured twice by the surgeon who is unaware of the induction regime. The induction drug in this group is STP 3 g/kg plus atracurium 0.2 mg /kg plus fentanyl 2 mcg/kg. After induction patient will be ventilated by mask and then ventilation will continue by LMA until the end of surgery. Pupil size will be measured 4 minute later by the same surgeon.

Category

Prevention

2

Description

In intervention group size of the pupil will be measured twice by the surgeon who is unaware of the induction regime. The induction drug in this group is STP 3 g/kg plus atracurium 0.2 mg /kg plus buprenorphine 0.3 mcg/kg. After induction patient will be ventilated by mask and then ventilation will continue by LMA until the end of surgery. Pupil size will be measured 4 minute later by the same surgeon

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fateme Zahra hospital
Full name of responsible person
Dr Najafi and Dr Akrami
Street address
Fateme Zahra hospital, Siraf Avenue
City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr Najafi, and Dr Akrami
Street address
Siraf Avenue
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person

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Person responsible for updating data

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Position
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Other areas of specialty/work
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Phone
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