

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of Flumazenil versus Aminophylline on cognitive and neuromotor emergence after Isoflurane anesthesia.

Protocol summary

Summary

The aim of this study was to compare the effect of Flumazenil and Aminophylline on cognitive and neuromotor emergence after Isoflurane based anesthesia. To conduct this randomized, placebo-controlled, double-blind study, 90 ASA-II patients who were scheduled to undergo orthopedic surgery under general anesthesia with nitrous oxide and Isoflurane were selected. Midazolam 0.03mg/kg and Morphine 2mg/kg was administered as premedication. Anesthesia was induced with Sodium Thiopental 5-6mg/kg and Atracurium 0.5-0.6mg/kg and controlled ventilation was maintained with 50%N₂O+50%O₂+Isoflurane. Isoflurane and N₂O were discontinued at the end of surgery. A coded ampule containing either 1mg Flumazenil or Aminophylline 2mg/kg or an equal volume (10cc) of saline was administered when the patient began to awaken. Vigilance was assessed by eye opening(spontaneous or command), limb movement (spontaneous or command), showing tongue on command, recall of age, recall of date of birth, recall of telephone number, simple arithmetic (2*3,4+7,etc.). Neurological recovery was evaluated by the papillary light reflex, the eyelash reflex and the absence of Babinski reflex. The following outcomes were measured at 5, 10, 20, 30, 40, 50 and 60 minutes after the injection of the test drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801261815N1**

Registration date: **2009-10-10, 1388/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-10-10, 1388/07/18

Registrant information

Name

Laleh Dehghanpisheh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1636 3955

Email address

ldehghan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2007-06-01, 1386/03/11

Expected recruitment end date

2008-07-01, 1387/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of Flumazenil versus Aminophylline on cognitive and neuromotor emergence after Isoflurane anesthesia.

Public title

A comparative study of Flumazenil versus Aminophylline on cognitive and neuromotor emergence after Isoflurane anesthesia.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: ASAII-II, age 14 to 65y/o, operation less than 3 hours
Exclusion criteria: benzodiazepine ingestion within two weeks prior to the study, chronic benzodiazepine use, presence of respiratory and cardiovascular diseases, pregnancy, motor system dysfunction, renal and liver diseases, sensitivity to Flumazenil or benzodiazepine, ASAIII-IV, substance abuse or psychiatric problems

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Midazolam 0.03mg/kg and Morphine 2mg/kg was administered as premedication. Anesthesia was induced with sodium thiopental 5-6mg/kg and atracurium 0/5-0/6mg/kg and controlled ventilation was maintained with 50%N2O+50%O2+Isoflurane. Isoflurane and N2O were discontinued at the end of surgery . A coded ampule containing either 1mg Flumazenil or Aminophylline 2mg/kg or an equal volume (10cc) of saline was administered when the patient began to awaken.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences and Health Services

Street address

Central building of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Postal code

Approval date

empty

Ethics committee reference number

3749-86

Health conditions studied

1

Description of health condition studied

Volatile anesthetics

ICD-10 code

Y48.0

ICD-10 code description

Inhaled anaesthetics

Primary outcomes

1

Description

Level of consciousness

Timepoint

5-10-20-40-50-60minute after injection of drugs

Method of measurement

Asking from the patients

2

Description

Neuromotor emergence

Timepoint

5-10-20-40-50-60minute after injection of drugs

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Flumazenil 1mg was administered after discontinuation of Isoflurane

Category

Treatment - Drugs

2

Description

Aminophylline 2mg/kg was administered after discontinuation of Isoflurane

Category

Treatment - Drugs

3

Description

Normal saline, 10cc was injected after discontinuation of Isoflurane

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Laleh dehghanpisheh

Street address

Anesthesiology ward, Chamran hospital, Chamran Blvd.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of Medical Sciences

Full name of responsible person

Dr. Afshin Amini

Street address

Shiraz university of Medical Sciences

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences and Health Services

Full name of responsible person

Dr. Asef Parviz Kazemi

Position

Anesthesiologist, Associate Professor

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

Chamran hospital

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

Dr. Laleh Dehghanpisheh

Position

Resident of Anesthesiology

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

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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