

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Assessment of different doses of aminophylline on decreasing recovery time and EEG during recovery based on BFI (Brain Function Index) after Isoflurane anesthesia in Trunk surgery.

Protocol summary

Summary

This study evaluates effects of 1 and 5 mg/kg Aminophylline injection on rapidity of brain awareness (awakening) and lowering recovery time based on EEG and prevalence of adverse effects of Aminophylline on 102 patients with following condition: Inclusion criteria: patients with ASA, class 1 & 2; patients between 15 to 70 years old; weight more than 40 kg. Exclusion criteria: patients with asthma (or similar diseases) in whom aminophylline is needed during surgery or during recovery; patients with liver failure or cardiac failure (cor pulmonale); neurologic or psychologic diseases which can cause seizure; drugs which affect brain activity including tranquilizers and CNS stimulants; serum albumin less than 2gr/dl; aminophylline injection during surgery for any reason; labetalol or other similar drugs injection (affecting cardiovascular system) during surgery for any reason. This randomized trial takes place on patients undergoing abdominal surgery with general anesthesia and tracheal intubation maintained by Isoflurane. At the end of surgery after discontinuing Isoflurane, all patients divided in three groups: Group 1: Aminophylline 1 mg/kg Group 2: Aminophylline 5 mg/kg Group 3: Placebo/witness EEG is monitored based on BFI during recovery time in all groups. We compare rapidity of awareness from anesthesia, rapidity of EEG changes based on BFI, and possible side effects in all three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403073773N11**
Registration date: **2015-08-02, 1394/05/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-02, 1394/05/11

Registrant information

Name

Farsad Imani

Name of organization / entity

Tehran University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2015-04-04, 1394/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of different doses of aminophylline on decreasing recovery time and EEG during recovery based on BFI (Brain Function Index) after Isoflurane anesthesia in Trunk surgery.

Public title

Assessment of Aminophylline on decreasing recovery time after general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing elective Trunk surgery with general anesthesia ;patients with ASA, class 1 & 2;patients between 15 to 70 years old;weight more than 40 kg.Exclusion criteria :patients with asthma (or similar diseases) in whom aminophylline is needed during surgery or during recovery; patients with liver failure or cardiac failure (cor pulmonale);neurologic or psychologic diseases which can cause seizure;drugs which affect brain activity including tranquilizers and CNS stimulants (eg. Amphetamine);serum albumin less than 2gr/dl (which lowers drug- plasma protein binding and increases drug effects);aminophylline injection during surgery for any reason;labetalol or other similar drugs injection (affecting cardiovascular system) during surgery for any reason.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

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**

Vice-chancellor for research, Tehran University of Medical Sciences

Street address

Ghods cross, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2014-02-16, 1392/11/27

Ethics committee reference number

9011174001

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

brain signals

ICD-10 code

G96.8

ICD-10 code description

Other specified disorders of central nervous system

2**Description of health condition studied**

Recovery time

ICD-10 code

G96.9

ICD-10 code description

Disorder of central nervous system, unspecified

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

Patient's stay time at PACU (Post Anesthesia Care Unit)

Timepoint

From discontinuing of anesthesia till discharge of PACU

Method of measurement

minute

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

Brain signals

Timepoint

During anesthesia and recovery time

Method of measurement

BFI (Brain Function Index)

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

In group 1, after cleaning of forehead with alcohol and adhesion of leads, EEG monitoring started based on BIS. All patients received midazolam 60 mic g/kg and fentanyl 2 mic g/ kg as pre-medication. Induction of anesthesia performed by thiopental 5mg/kg and muscle relaxation with atracurium 0.5 mg/ kg followed by tracheal intubation. Anesthesia maintained by Isoflurane in order to remains BIS between 40 to 60. In order to maintain 90-95% twitch inhibition, atracurium injected during surgery. At the end of surgery and discontinuation of Isoflurane , aminophylline 1 mg/ kg injected

intravenously. EEG monitored based on BIS during recovery period. Rapidity of awakening from anesthesia , rapidity of increasing brain waves based on BSI and possible side effects will be recorded.

Category

Other

2**Description**

In group 2, after cleaning of forehead with alcohol and adhesion of leads, EEG monitoring started based on BIS. All patients received midazolam 60 mic g/kg and fentanyl 2 mic g/ kg as pre-medication. Induction of anesthesia performed by thiopental 5mg/kg and muscle relaxation with atracurium 0.5 mg/ kg followed by tracheal intubation. Anesthesia maintained by Isoflurane in order to remains BIS between 40 to 60. In order to maintain 90-95% twitch inhibition, atracurium injected during surgery. At the end of surgery and discontinuation of Isoflurane , aminophylline 5 mg/ kg injected intravenously. EEG monitored based on BIS during recovery period. Rapidity of awakening from anesthesia , rapidity of increasing brain waves based on BSI and possible side effects will be recorded.

Category

Other

3**Description**

In group 3, after cleaning of forehead with alcohol and adhesion of leads, EEG monitoring started based on BIS. All patients received midazolam 60 mic g/kg and fentanyl 2 mic g/ kg as pre-medication. Induction of anesthesia performed by thiopental 5mg/kg and muscle relaxation with atracurium 0.5 mg/ kg followed by tracheal intubation. Anesthesia maintained by Isoflurane in order to remains BIS between 40 to 60. In order to maintain 90-95% twitch inhibition, atracurium injected during surgery. At the end of surgery and discontinuation of Isoflurane ,Placebo injected intravenously. EEG monitored based on BIS during recovery period. Rapidity of awakening from anesthesia , rapidity of increasing brain waves based on BSI and possible side effects will be recorded.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Dr Farsad Imani

Street address

Hasanabad Sq., Imam Khomeini St.

City

Tehran

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

Tehran University of Medical Sciences, Medical school

Full name of responsible person

Dr Farsad Imani

Street address

Ghods cross, Keshavarz Blvd

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Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences, Medical school

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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Farsad Imani

Position

Professor assistant

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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