

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Population pharmacokinetics of propofol in patients undergoing surgical procedure

Protocol summary

Summary

This study intends to characterize propofol pharmacokinetics parameters that it may leads to specifying the ideal dose. Inclusion criteria: ASAclass-1; Age between 15-55 years. Exclusion criteria: ASAclass-2; Addiction; Liver, kidney, cardiac disease; Sensivity for egg; Hemodynamic instability. 30 patients presenting for general anesthesia were enrolled. They were equally divided into two groups: A (50µg/kg/min) and B (100ug/kg/min). All patients were administered same drugs in anesthesia induction with doses according to their weights and followed by a constant infusion rate of propofol. If possible, blood samples were collected at 0, 2, 5, 10, 15, 30, 45, 60 minutes during infusion and then 0, 2, 5, 10, 15, 30, 45, 60, 120, 180 minutes after the stop of infusion. Propofol concentration in plasma were measured using HPLC method..

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013063012365N2**

Registration date: **2015-01-01, 1393/10/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-01, 1393/10/11

Registrant information

Name

Saeed Rezaee

Name of organization / entity

Jondishpour university of medical science, faculty of pharmacy

Country

Iran (Islamic Republic of)

Phone

+98 916 301 9067

Email address

s.rezaee@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Population pharmacokinetics of propofol in patients undergoing surgical procedure

Public title

Population pharmacokinetics of propofol infusion

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: ASAclass-1; Age between15-55 years.
Exclusion criteria: ASAclass-2; Addiction; Liver, kidney, cardiac disease; Sensivity for egg; Hemodynamic instability.

Age

From **17 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan avenue, Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2012-07-21, 1391/04/31

Ethics committee reference number

ETH-542

Health conditions studied

1

Description of health condition studied

General anesthesia

ICD-10 code

Y 48.2

ICD-10 code description

Other and unspecified general anaesthetics

Primary outcomes

1

Description

Plasma concentration of propofol

Timepoint

If possible blood samples are collected at 0, 2, 5, 10, 15, 30, 45, 60 minutes during infusion and then 0, 2, 5, 10, 15, 30, 45, 60, 120, 180 minutes after the end of infusion.

Method of measurement

Blood sampling with the volume of 2ml and analyzing the

concentration with HPLC

2

Description

Weight

Timepoint

Before transferring to operation room

Method of measurement

Scale

3

Description

Height

Timepoint

Before transferring to operation room

Method of measurement

Meter

4

Description

Age

Timepoint

Before transferring to operation room

Method of measurement

Match with birth certificate

5

Description

Sex

Timepoint

Before transferring to operation room

Method of measurement

Match with birth certificate

Secondary outcomes

empty

Intervention groups

1

Description

In A group, propofol is infused with infusion rate equals to 50µg/kg/min.

Category

Treatment - Drugs

2

Description

In B group, propofol is infused with infusion rate equals to 100µg/kg/min.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr Mohammad Reza Pipelzadeh

Street address

Imam Khomeini hospital, Azadegan street, Ahvaz, Iran

City

Ahvaz

2

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Dr Mohammad Reza Pipelzadeh

Street address

Golestan hospital, Golestan street, Ahvaz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader Saki

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan avenue, Ahvaz, Iran

City

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

Yes

Title of funding source

Ahvaz Jundishapur 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

School of pharmacy, Ahvaz Jundishapur University of
Medical Sciences

Full name of responsible person

Dr Saeed Rezaee

Position

PhD of pharmaceuticals, Assistant professor

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