

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effects of Sleep deprivation on depth of anesthesia after induction of anesthesia with propofol in patient with orthopedic surgery in Mashhads Ghaem Hospital

Protocol summary

Summary

The aim of study is finding Effects of Sleep deprivation on depth of anesthesia after induction of anesthesia with propofol . Inclusion criteria:Patient Since November 2013 till end of sampeling ; emergency orthopedics surgery
Exclusion criteria : sleep disorders and insomnia; patients taking sedative and stimulant drugs, history of drug abuse ; history of seizure or a CNS disorder ; age> 60 yrs ; age <15 yrs 27 patients who will supposed to undergo emergency orthopedics surgery were enrolled in the study. Patients' characteristics including duration of sleep 24 hour before operation were recorded in a questionnaire. All patients will anesthetized by fentanyl 2µg/kg plus propofol 2mg/kg as the induction agents of anesthesia. Monitoring of the depth of anesthesia will accomplished using Bispectral index (BIS) monitor, model Vista. Distribution of all numeric variables of age, depth of anesthesia and sleep can be checked with the Kolmogorov-Smirnov test.effect of duration of sleep 24 hours before anesthesia asses by regression model and this will bi significant and sleep increase BIS and increase anesthesia depth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412278143N2**
Registration date: **2015-01-21, 1393/11/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-21, 1393/11/01

Registrant information

Name

Ehsanolah Ghorbanian

Name of organization / entity

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Mashhad Unevercity of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-11-01, 1392/08/10

Expected recruitment end date

2014-10-30, 1393/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Sleep deprivation on depth of anesthesia after induction of anesthesia with propofol in patient with orthopedic surgery in Mashhads Ghaem Hospital

Public title

Effects of Sleep deprivation on depth of anesthesia after induction of anesthesia with propofol

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:Patient Since November 2013 till end of

sampling ; emergency orthopedics surgery Exclusion criteria : sleep disorders and insomnia; patients taking sedative and stimulant drugs, history of drug abuse ; history of seizure or a CNS disorder ; age> 60 yrs ; age <15 yrs

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences ethical Committee

Street address

Mashhad University of Medical Sciences ethical Committee, Ghoreshi bilding, Daneshgah Av

City

Mashhad

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

900876

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

Depth of Anesthesia

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

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

sleep

Timepoint

immediately before intervention

Method of measurement

self report

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

depth of anesthesia

Timepoint

in intervention

Method of measurement

BIS

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

All patients will anesthetized by fentanyl 2µg/kg plus propofol 2mg/kg as the induction agents of anesthesia.

Category

Other

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

Operation room of Ghaem Hospital

Full name of responsible person

Alireza Sharifian Attar

Street address

Ghaem hospital , Ahmadabad Ave.

City

Mashhad

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

Mashhad University of Medical Sciences, Anesthesiology Department

Full name of responsible person

Alireza Sharifian Attar

Street address

Ghaem Hospital, Ahmadabad Ave.

City

Mashhad

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences, Anesthesiology Department
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
Anesthesiology Department
Full name of responsible person
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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