

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of different doses of midazolam for amnesia and sedation in general anesthesia

Protocol summary

Summary

Many patients prefer to be sedated and amnesic during surgical procedures. We investigated the effective and safe dose of intravenous midazolam for sedation and amnesia during general anesthesia in patients undergoing outpatient surgical procedure. 92 patients aged 20–60 years scheduled for general anesthesia received midazolam 1 or 3 mg intravenously 5min before entering the operating room. Premedication was performed with fentanyl 2 microgram/kg. General anesthesia was performed with 4 mg/kg sodium thiopental. Blood pressure, heart rate, respiratory rate, percutaneous oxygen saturation (SpO₂), were measured every 5min for 30min. Memory during surgery was also investigated by recall of poster and events.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101293468N5**

Registration date: **2011-04-04, 1390/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-04, 1390/01/15

Registrant information

Name

Mohammad Reza Hajiesmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00983516227747-00983517232422

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hajiesmaeili@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of different doses of midazolam for amnesia and sedation in general anesthesia

Public title

Evaluation of different doses of midazolam for amnesia and sedation in general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- ASA Class=1,2; 2- Elective outpatient surgical procedure under general anesthesia; 3- age below 60 years; 4- weight between 50-100 kilogram; 5- No visual disturbance; 6- No auditory disturbance; 7- No memory disturbance; 8- No tranquilizer drug consumption. Exclusion criteria: known allergy to study drug.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Science and Health Services

Street address

Shhid Bahonar Square

City

Yazd

Postal code

Approval date

2008-09-23, 1387/07/02

Ethics committee reference number

1064

Health conditions studied

1

Description of health condition studied

amnesia

ICD-10 code

F44.0

ICD-10 code description

Dissociative amnesia

Primary outcomes

1

Description

amnesia

Timepoint

after 4 hours

Method of measurement

events and poster recall

Secondary outcomes

empty

Intervention groups

1

Description

in group 1 patiens were received intravenous midazolam 1 milligram just before entering to the operating room.

Category

Prevention

2

Description

in group 2, patients were given 3 milligram intravenously just before entering to the operating room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Shekoufeh Behdad

Street address

Shahid Sadoughi hospital , Safaieeh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Hassan Mozaffari Khosravi

Street address

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences and Health Services

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences and Health Services

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

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Person responsible for general inquiries

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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