

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of Midazolam on perception and consciousness during surgery

Protocol summary

Summary

Intraoperative awareness and understanding are of the unpleasant complications of anesthesia which are essential to reduce due to psycho-physiological. This study was done to investigate the effects of Midazolam for reducing the complication occurs during the surgery. This study was done on patients admitted for elective surgery, general surgery, urology - orthopedic surgery with a length of about one hour in class 1 and 2 ASA classification. Patients with hearing problems, psychiatric illness, drug addiction and using drugs affecting the nervous and mental who were referred to ICU after operation because of specific condition will be excluded from study. Anesthesia technicians and the intern were unaware of members of the both groups. The patients were randomly assigned into two groups of intervention and control. 2.5 mg of Midazolam was injected to intervention group about 15 minutes before induction of anesthesia. Both groups were induced by 5mg/kg of Thiopental and 1.5mg/kg of intravenous Midazolam and then were anesthetized pre-oxygenation. The anesthesia continued using Halothane 0.5% and N2o and Oxygen in proportion of 50%. Muscle relaxation is done using Atracurium 2/0. During surgery, blood pressure, heart rate, tearing and requiring of sedative increasing depth of anesthesia will be examined. After the surgery the patient's intelligence, and 1 hour after surgery, pain and touch and hearing the conversation during the act, dream act in time, recalling memories were recorded in the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207086480N3**
Registration date: **2012-08-10, 1391/05/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-10, 1391/05/20

Registrant information

Name

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Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2012-07-13, 1391/04/23

Expected recruitment end date

2012-11-06, 1391/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Midazolam on perception and consciousness during surgery

Public title

Effect of Midazolam on perception and consciousness during surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who are candidate for elective surgery class A, Two ASA classification, 1 hour for operation length, the age ranges between 15-45 years old. Exclusion criteria: having every kind of hearing problems, neurological disease, addiction, using drugs affective for Psychiatry and patients who are referred to ICU after operation because of specific condition.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **154**

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

Shahrekord University of Medical Sciences

Street address

Kashani Boulevard

City

Sahrekord

Postal code

Approval date

2007-10-15, 1386/07/23

Ethics committee reference number

7-7-86

Health conditions studied

1

Description of health condition studied

Intraoperative awareness

ICD-10 code

R41

ICD-10 code description

Other symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description

Increasing depth of anesthesia

Timepoint

Intraoperation

Method of measurement

Questionnaire

2

Description

Recalling the memories

Timepoint

1 hour after operation

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Tearing

Timepoint

Intraoperation

Method of measurement

Questionnaire

2

Description

Tachycardia

Timepoint

Intraoperation

Method of measurement

Questionnaire

3

Description

Dream in action

Timepoint

1 hour after operation

Method of measurement

Questionnaire

4

Description

Hearing the conversation intraoperation

Timepoint

1 hour after operation

Method of measurement

Questionnaire

5

Description

pain

Timepoint

1 hour after operation
Method of measurement
Questionnaire

Intervention groups

1

Description

The intervention group receive 2.5 mg intravenous Midazolam 15 minutes before induction of anesthesia. After the pre-oxygenation they are placed under anesthesia with the 5 mg / kg of Thiopental and 1.5 mg/kg of Succinylcholine induction, continuation of anesthesia is done using Halothane 0.5% and N2o and oxygen in proportion of 50%. Muscle relaxation by Atracurium 2/0 is created.

Category

Other

2

Description

In the control group after pre-oxygenation they are placed under anesthesia induction with the 5 mg / kg of thiopental and 1.5 mg/ kg of Succinylcholine, continuation of anesthesia is done using Halothane 0.5% and N2o and oxygen in proportion of 50%. Muscle relaxation created by Atracurium 2/0 .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord ayatollah Kashani hospital

Full name of responsible person

Dr Ebrahim Pouria Monfared

Street address

Shariati Street

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmoud Mobasheri

Street address

Kashani boulevard

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research, Shahrekord 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

Ayatollah Kashani hospital

Full name of responsible person

Dr Ebrahim Pouria Monfared

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Ebrahim Pouria Monfared

Position

Anesthesiologist

Other areas of specialty/work

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Phone

+98 38 1226 4825

Fax

Email

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Web page address

Person responsible for updating data

Contact

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