

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of different doses of midazolam and preoperative anxiety on retrograde and anterograde amnesia in patients undergoing abdominal laparotomy under general anesthesia

Protocol summary

Study aim

The effects of different doses of midazolam and preoperative anxiety on retrograde and anterograde amnesia in patients undergoing abdominal laparotomy under general anesthesia

Design

120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy under GA at Rasoul Akram Hospital randomly assigned to, two groups with 60 persons a stressful or normal after the Amsterdam test Then, patients in each group are again divided into three groups of 20 each. This is performed by randomized block method, Patients are divided into 3 blocks and 6 blocks in each blocks of the three groups are existed in study. the study is done with tripel method and has a control group

Settings and conduct

In our study, 120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy under GA at Rasoul Akram Hospital were randomly assigned to two groups with 60 patients high - stress and Normal Then patients in each group were again divided into three groups of 20 each. To the first group midazolam As premed with dose of .02mg per kg and second one .04mg per kg will be injected. The third group will be the control group and will not receive midazolam. The registrant has no information about the type of drug.

Participants/Inclusion and exclusion criteria

Patients aged 20 to 60 years at risk of anesthesia 1 and 2 undergoing non-emergency abdominal laparotomy. Exclusion criteria included ASAIII risk, pregnant patients, patients with psychiatric disorders or taking sedative and antipsychotic medications, mental disorders, patients with visual or hearing impairment, patients with hepatic and renal impairment, and previous benzodiazepine use.

Intervention groups

The first group receive midazolam 02. mg / kg as premedication. The second group receive midazolam 04. mg / kg as premedication. Control group do not receive Midazolam

Main outcome variables

Amnesia

General information

Reason for update

Acronym

The American Society of Anesthesiologists (ASA) (GA) general anesthesia SpO2 stands for peripheral capillary oxygen saturation blood pressure(BP

IRCT registration information

IRCT registration number: **IRCT20200213046484N1**
Registration date: **2020-03-06, 1398/12/16**
Registration timing: **prospective**

Last update: **2020-03-06, 1398/12/16**

Update count: **0**

Registration date

2020-03-06, 1398/12/16

Registrant information

Name

Saied Amniati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 0317

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of different doses of midazolam and preoperative anxiety on retrograde and anterograde amnesia in patients undergoing abdominal laparotomy under general anesthesia

Public title

The effect of midazolam and anxiety on amnesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy undergoing GA at Rasool Akram Hospital

Exclusion criteria:

Patients with ASAIII risk The Pregnant patient Patients with psychiatric disorders or receiving sedative and antipsychotic medications Mental dysfunction Patients with visual or hearing impairment Patients with liver and kidney dysfunction Previous use of benzodiazepine

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

In our study, 120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy undergoing GA at Rasool Akram Hospital were randomly assigned to two groups of 60 high stress subjects after the Amsterdam test. And they will be normal. Then, patients in each group are again divided into three groups of 20 each. This is done by block randomization. Patients are divided into 3 and 6 blocks, each block having three study groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient and the injector and the registrant are unaware of the type of study, and the study will be a Triple Blind study.

Placebo

Not used

Assignment

Factorial

Other design features

In our study, 120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy undergoing GA at Rasool Akram Hospital were randomly assigned to two groups of 60 high stress subjects after the Amsterdam test. And they will be normal. Then the patients in each group are again divided into three groups of 20 each

Secondary Ids

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Rasool Akram Hospital; Mansouri St; Satarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.IUMS.FMD.REC.1398.505

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

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

Amnesia

Timepoint

Zero minutes (4 min before premedication), 2 (2 min

before premedication), 4 (immediately before premedication) 6 min (2 min after premedication), 8 (4 min after Premedication) and 10 (6 min after premedication)

Method of measurement

Cards with simple photos

Secondary outcomes

1

Description

Blood pressure

Timepoint

minutes 1,2,3 after intubation

Method of measurement

NIBP

2

Description

Heart rate

Timepoint

Minutes 1,2,5after intubation

Method of measurement

Monitoring device

3

Description

Decrease in oxygen saturation

Timepoint

Minutes 1,2,5after intubation

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention group: : Midazolam .02mg / kg , One dose is injected as a premedication.

Category

Treatment - Drugs

2

Description

Intervention group: Midazolam .04mg / kg ,One dose is injected as a premedication.

Category

Treatment - Drugs

3

Description

Control group:do not take midazolam

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Azadeh Habibi

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Rasoul Akram Hospital; Mansouri st; Satarkhan Ave

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Sponsors / Funding sources

1

Sponsor

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Azadeh Habibi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Personal information including patients 'age and sex ,anxiety and the effects of different doses of midazolam on amnesia and hemodynamic variables including blood pressure and heart rate may be disclosed if needed without disclosure and with ethical guidelines

When the data will become available and for how long

After publish of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The Current analysis in medical research subject to ethical standards in studies

From where data/document is obtainable

Dr. Azadeh Habibi, Rasoul-e-Akram Hospital, Mansouri St., Sattarkhan St., Tehran, IR. 1445613131

Tel,0098216435232 Email:azade_h84@yahoo.com
What processes are involved for a request to access data/document

Email request submitted to person
Comments