Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 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 metod , 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 metod 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 recieve 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

amniati.s@iums.ac.ir

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 ofmidazolam 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
Age
From **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 size
Target 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 Rasoul 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
n our study, 120 patients aged 20 to 60 years at risk of ASA1-2 undergoing non-emergency abdominal laparotomy undergoing GA at Rasoul 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
Rasoul 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

Street address

Rasoul Akram Hospital; Mansouri st; Satarkhan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Anesthesiology

Street address

Rasoul Akram Hospital ; mansouri st ;Satarkhan Ave

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Person responsible for scientific 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

Anesthesiology

Street address

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Person responsible for updating data

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Full name of responsible person

Saied Amniati

Position

Assistant Professor

Latest degree

Specialist

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