

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

A comparison of dexmedetomidine and midazolam for sedation in transesophageal echocardiography.

Protocol summary

Summary

The aim of this prospective, randomized study was to compare the standard regimen of midazolam with infusion of dexmedetomidine for sedation during transesophageal echocardiography. Inclusion criteria was patients scheduled for TEE and ages of 18-60 years. Patients were excluded of study if they have previous TEE and upper digestive system endoscopic examinations; emergency examinations; pregnancy; mechanical ventilation; patients with psychiatric and emotional disorder; history of addiction; history of allergic reaction. In this study, 60 patients scheduled for TEE participated in the study. TEE examinations were performed by two skilled operators who were blinded to the study. All patients were anaesthetized topically in the oropharynx with 10% aerosol solution of lidocaine until the gag reflex was suppressed. After written informed consent, blood pressure, heart rate and pulse oximetry were monitored and recorded. Patients received either IV midazolam (group M, 2 mg bolus) or an infusion of dexmedetomidine (group D, 1 mcg/kg/min, reduced to 0.2 mcg/kg/min after probe insertion). Sedation was assessed using Ramsey sedation score during echocardiography. We recorded blood pressure, SpO₂ and heart rate during echocardiography and recovery. Time-to-discharge, duration of procedure, side effect of drugs, complications and Patients' satisfaction was assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308095381N7**

Registration date: **2015-01-27, 1393/11/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-27, 1393/11/07

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22 38296

Email address

nbanihashem@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research Babol University of Medical Sciences

Expected recruitment start date

2013-06-19, 1392/03/29

Expected recruitment end date

2013-09-11, 1392/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of dexmedetomidine and midazolam for sedation in transesophageal echocardiography.

Public title

A comparison of dexmedetomidine and midazolam for sedation in transesophageal echocardiography.

Purpose

Treatment

Inclusion/Exclusion criteria

exclusion criteria: previous TEE and upper digestive system endoscopic examinations; emergency examinations; pregnancy; mechanical ventilation; patients with psychiatric and emotional disorder; history of addiction; history of allergic reaction. Inclusion criteria: patients scheduled for TEE; patients with a history of transient cerebral ischaemic attack; ages of 18-60 years

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Babol University of Medical Sciences

Street address

Daneshgah Sq - Ganjafrooz Ave

City

babol

Postal code

Approval date

2013-06-11, 1392/03/21

Ethics committee reference number

9235635

Health conditions studied

1

Description of health condition studied

Transient cerebral ischaemic attack

ICD-10 code

G45.9

ICD-10 code description

Transient cerebral ischaemic attack, unspecified

Primary outcomes

1

Description

sedation level

Timepoint

Observation during echography

Method of measurement

Ramsy sedation score

2

Description

patient satisfaction

Timepoint

after echocardiography

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Recovery time

Timepoint

end of TEE

Method of measurement

minute

2

Description

nausea and vomiting

Timepoint

End of TEE

Method of measurement

Direct inspection and history

3

Description

Hypoxia

Timepoint

during and after TEE

Method of measurement

pulse oximetry

4

Description

blood pressure

Timepoint

during and after TEE

Method of measurement

Noninvasive cuff measurment

5

Description

heart rate

Timepoint

during and after TEE
Method of measurement
pulse counting

Intervention groups

1

Description

The first group will received 2 mgmidazolam before the procedure and if needed additional midazolam will be added.

Category

Treatment - Drugs

2

Description

The second group will received an infusion of dexmedetomidine1 mcg/kg/minand reduced to 0.2 mcg/kg/min after probe insertion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Ruhani Hospital

Full name of responsible person

Dr Nadia Banihashem

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of Research Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 112238296

Fax

Email

nbanihashem@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

nbanihashem@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work**Street address**

Anesthesiology Department, Ruhani Hospital,
Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code**Phone**

+98 11 1223 8296

Fax**Email**

nbanihashem@yahoo.com

Web page address**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