Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, SpO(2) 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

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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 forTEE; patients with a history of transient cerebral ischaemic attack؛ages of 18-60years
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 analoge 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 measurrment

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

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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