

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of total intravenous anesthesia with Propofol and Midazolam on liver and renal function after tracheal resection & anastomosis surgery

Protocol summary

Summary

Many factors contribute to postoperative hepatic and renal injury including anesthetic agents and type of surgery. This clinical study is planned to evaluate the effect of total intravenous anesthesia with Propofol and Midazolam on liver enzymes and renal function in the patients undergone tracheal resection and anastomosis surgery. 70 American Society of Anesthesiologists physical status I and II patients scheduled for elective tracheal resection and anastomosis surgery, are randomly divided into 2 groups to receive either Propofol (n = 35) or Midazolam (n = 35) for maintenance of anesthesia. Induction of anesthesia is similar in both groups. Preoperative serum levels of liver enzymes and renal tests including aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), total bilirubin (TBil), and gamma-glutamyl transpeptidase (GTP), BUN and creatinin are compared with those on the first and third postoperative days in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110815322N1**

Registration date: **2014-01-17, 1392/10/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-17, 1392/10/27

Registrant information

Name

Shideh Dabir

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tracheal Diseases Research Center, National Research Institute of Tuberculosis & Lung Diseases

Expected recruitment start date

2011-09-06, 1390/06/15

Expected recruitment end date

2013-12-15, 1392/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of total intravenous anesthesia with Propofol and Midazolam on liver and renal function after tracheal resection & anastomosis surgery

Public title

The effect of Propofol and Midazolam on liver and renal tests in patients undergoing tracheal resection surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Exclusion criteria: liver or renal disease; DM; preoperative baseline elevated level of liver enzymes and renal tests; alcohol or substance abuse; known allergy to study drugs; ASA class 3 or higher. Inclusion

criteria: normal preoperative baseline level of liver enzymes and renal tests; age ranging 16-60 years; ASA class 1 and 2.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

National Research Institute of Tuberculosis & Lung Diseases, Masih Daneshvari Hospital

Street address

Research office, Masih Daneshvari Hospital, Darabad, Nivaran

City

Tehran

Postal code

1955841452

Approval date

2009-04-09, 1388/01/20

Ethics committee reference number

640

Health conditions studied

1

Description of health condition studied

Intravenous anesthetic drug side effect

ICD-10 code

Y 48.1

ICD-10 code description

Parenteral anaesthetics

Primary outcomes

1

Description

Aspartate aminotransferase (AST)

Timepoint

before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

2

Description

Alanine aminotransferase (ALT)

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

3

Description

Total Bilirubin

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

4

Description

alkaline phosphatase

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

5

Description

G-glutamyltransferase

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

6

Description

Lactate dehydrogenase

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

7

Description

Blood Urea Nitrogen (BUN)

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

8

Description

Creatinine

Timepoint

Before induction of anesthesia, on the first, and third postoperative days.

Method of measurement

Liasys AMS test

Secondary outcomes

1

Description

Heart rate

Timepoint

Before induction of anesthesia (base line), 30 minutes after Induction of anesthesia, 1,2,3 and 4 hours after initiation of surgery, at the end of surgery

Method of measurement

Electrocardiogram

2

Description

Mean arterial blood pressure (MAP)

Timepoint

Before induction of anesthesia (base line),30 minutes after Induction of anesthesia, 1,2,3 and 4 hours after initiation of surgery, at the end of surgery

Method of measurement

sphygmomanometer

3

Description

Percent of arterial oxygen saturation (Spo2)

Timepoint

Before induction of anesthesia (base line),30 minutes after Induction of anesthesia, 1,2,3 and 4 hours after initiation of surgery, at the end of surgery

Method of measurement

pulse oximetry

Intervention groups

1

Description

Patients in the Midazolam group received continuous infusions of Midazolam 0.02- 0.04 mg/kg/hr for maintenance of anesthesia during surgery.

Category

Other

2

Description

Patients in the Propofol group received continuous infusions of propofol 100-200 µg/kg/min for maintenance of anesthesia during surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr. Tahereh Parsa

Street address

Department of Anesthesiology, Masih Daneshvari Hospital,Darabad, Niavaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Research Institute of Tuberculosis and Lung Diseases, Tracheal Diseases Research Center

Full name of responsible person

Iman Ghaydi

Street address

Department of Anesthesiology, Masih Daneshvari Hospital Darabad, Niavaran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Research Institute of Tuberculosis and Lung Diseases, Tracheal Diseases Research Center

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

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Dr. Tahereh Parsa

Position

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

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Fax

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