Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Target Controlled Infusion of Remifentanil with Propofol or Desflurane under Bispectral Index Guidence: quality of anesthesia and recovery profile

Protocol summary

Summary

Our objective is to examine the clinical properties of two anesthetic regimens, propofol TCI or desflurane using remifentanil in a target-controlled infusion (TCI) under bispectral index (BIS) guidance during ear, nose, and throat (ENT) procedures. Forty consenting patients scheduled for ENT procedures will be prospectively studied, and they are included in one of the two groups: TCI (group TCI) or desflurane (group DES). General anaesthesia will be induced with 3 ng mL-1 and 4 µg mL-1 effect site concentrations (Ce) of remifentanil and propofol, respectively, with TCI system. After intubation, while propofol infusion is continued in the TCI group, it is ceased in the DES group and desflurane with an initial delivered fraction of 6 % is administered. The Ce of propofol infusion and inspired fraction of desflurane is adjusted in order to keep BIS 50 ± 10.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104236266N1**
Registration date: **2011-05-09, 1390/02/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-09, 1390/02/19

Registrant information

Name

Ahmet Mahli

Name of organization / entity

Gazi University Faculty of Medicine, Department of Anaesthesiology and Reanimation

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Turkey

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Recruitment status

Recruitment complete

Funding source

Gazi University

Expected recruitment start date

2009-04-01, 1388/01/12

Expected recruitment end date

2010-04-01, 1389/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Target Controlled Infusion of Remifentanil with Propofol or Desflurane under Bispectral Index Guidence: quality of anesthesia and recovery profile

Public title

Target Controlled Infusion of Remifentanil with Propofol or Desflurane under Bispectral Index Guidence: quality of anesthesia and recovery profile

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18-65 who are candidate for ENT procedures Exclusion criteria: Taking any sedative or analgesic drugs 24 hours before surgery, significantly hypertensive (diastolic blood pressure less than100 mmHg) or hypotensive (systolic blood pressure

less 100 mmHg) and presence the signs of bradyarrhythmic heart disorders

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional Ethics Committee

Street address
Gazi University Faculty of Medicine, Department of Anaesthesiology and Reanimation

City
Ankara

Postal code
06500

Approval date
2009-03-01, 1387/12/11

Ethics committee reference number
01.03.2009

Health conditions studied

1

Description of health condition studied
Quality of anesthesia and recovery profile

ICD-10 code
Y48.2

ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
Mean arterial pressure

Timepoint
During anesthesia

Method of measurement
Equipment

Secondary outcomes

1

Description
Heart rate

Timepoint
During anesthesia

Method of measurement
Physical exam

2

Description
Early emergence from anesthesia

Timepoint
During anesthesia

Method of measurement
Physical exam

3

Description
Patients’ aldrete score (ARS)

Timepoint
During anesthesia

Method of measurement
Physical exam

Intervention groups

1

Description
TCI geoup; general anaesthesia will be induced with 3 ng mL-1 and 4 µg mL-1 effect site concentrations (Ce) of remifentanil and propofol

Category
Treatment - Drugs

2

Description
DES group; general anaesthesia will be induced with 3 ng mL-1 and 4 µg mL-1 effect site concentrations (Ce) of remifentanil and propofol, respectively, after intubation, propofol infusion is ceased in the DES group and desflurane with an initial delivered fraction of 6 % is administered

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gazi University Faculty of Medicine, Department of Anaesthesiology and Reanimation
Full name of responsible person
Street address
City
Ankara

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
none
Full name of responsible person
none
Street address
none
City
none
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
none
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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Full name of responsible person
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Position
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Other areas of specialty/work
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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