

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Target Controlled Infusion of Remifentanyl with Propofol or Desflurane under Bispectral Index Guidance: 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 remifentanyl 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 remifentanyl 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

Country

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 Remifentanyl with Propofol or Desflurane under Bispectral Index Guidance: quality of anesthesia and recovery profile

Public title

Target Controlled Infusion of Remifentanyl with Propofol or Desflurane under Bispectral Index Guidance: 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 than 100 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

TCl group; general anaesthesia will be induced with 3 ng mL⁻¹ and 4 µg mL⁻¹ effect site concentrations (Ce) of remifentanyl 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 remifentanyl 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

Gazi University Faculty of Medicine, Department of
Anaesthesiology and Reanimation

Full name of responsible person

Ahmet Mahli

Position

Assistant Professor

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