

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of target-controlled infusion anesthesia and balanced anesthesia in renal transplantation surgery

Protocol summary

Summary

40 patients with end stage renal disease, age between 18 and 60 years and ASA class II-III will be enrolled in the study and randomly allocated into two treatment groups. In the first group (TCI), patients will receive remifentanyl (4ng/ml) and propofol (4micg/ml) as effect site concentration target, respectively, during anesthesia and in the second group patients will receive sufentanil (10-15 mic bolus) and propofol (1.5 mg/kg) for induction and then N2O and Isoflurane(<1 MAC)for maintenance of anesthesia. Patients with any dependence to opioids and sedatives or with ASA more than III will be excluded from the study. Vital signs and BIS will be measured and compared in 7 different time points. Presence of nausea and vomiting, urine output and pain severity will be compared between two groups during 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710011361N2**
Registration date: **2009-01-05, 1387/10/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-01-05, 1387/10/16

Registrant information

Name

Naser Yeganeh

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Pro-vice-chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2008-12-30, 1387/10/10

Expected recruitment end date

2009-05-30, 1388/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of target-controlled infusion anesthesia and balanced anesthesia in renal transplantation surgery

Public title

Comparison of two methods of anesthesia for renal transplantation surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-60 years, ASA class II-III, End Stage Renal Disease candidate for renal transplantation
Exclusion criteria: ASA class more than III, denial of patients, any dependence to opioids or sedative agents.

Age

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

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid-Beheshti Bulvard

City

Kermanshah

Postal code

Approval date

2008-01-29, 1386/11/09

Ethics committee reference number

420/4279

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.0

ICD-10 code description

End-stage Renal Disease

Primary outcomes

1

Description

Vital signs during renal transplantation surgery

Timepoint

T1: before induction of anesthesia, T2: immediately after intubation, T3: after skin incision, T4: before declamping renal artery, T5: after skin suture, T6: after extubation, T7: in the recovery room

Method of measurement

Clinical examination and non-invasive blood pressure measurement

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

every 2 h in first 24 h after operation

Method of measurement

observation,clinical examination

2

Description

Pain

Timepoint

Every 2 hour during 24 hours after operation

Method of measurement

visual analoge scale

3

Description

Urine output

Timepoint

Every 2 hour during 24 hours after operation

Method of measurement

Volume of urine output per hour

Intervention groups

1

Description

Remifentanil and Propofol with target controlled method

Category

empty

2

Description

IV induction with Sufentanil and Propofol and inhalational anesthesia with isoflurane and N2O for maintenance

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Naser Yeganeh - Mohamad Musavi

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pro-vice-chancellor for Research, Kermanshah
University of Medical Sciences

Full name of responsible person

Dr. H.Khazaie, Pro-vice chancellor for Research,

Street address

Shahid-Beheshti Boulevard

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Pro-vice-chancellor for Research, Kermanshah 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**

Imam Reza Hospital

Full name of responsible person

Naser Yeganeh

Position

Anesthesiologist/Assistant Professor

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Position

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Other areas of specialty/work**Street address****City****Postal code****Phone****Fax****Email**

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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