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 remifentanil (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
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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 comittee 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 Bulvard
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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

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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