Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison BIS Monitoring with Clinical Monitoring in recovery model of patients undergoing open kidney surgery under general anesthesia

Protocol summary

Summary

The purpose of this study is to compare BIS Monitoring with Clinical Monitoring in recovery Model of patients undergoing open kidney surgery under general anesthesia. All patients undergoing open kidney surgery from March to October 2015 are enrolled. Patients are randomly divided two groups, BIS (B) and control (C). Both groups are anesthetized by an identical method. Anesthetic management of these patients involves the measurement of HR, NIBP, ECG and pulse oximetry at intervals of 5 minutes. Check the depth of anesthesia in Group C measure by checking the heart rate, blood pressure, tears, sweat and pupil size that if increase 20% from initial baseline or change in any of the cases cited, narcotic will inject into the patient. In Group B, BIS monitoring is used. BIS between 60-40 is considered normal and this range will be maintained for the entire duration of surgery. If BIS increased to over 60, despite initial administration of propofol, narcotic is injected into the patient. After surgery, the eye opening time, oral response to verbal stimuli time, extubation time, stay in recovery time, the total amount of narcotic injecting during and after surgery and the first time that use narcotic will record. All data will be analyzed using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042111766N2**
Registration date: **2015-05-17, 1394/02/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-17, 1394/02/27

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Guilan university of medical sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison BIS Monitoring with Clinical Monitoring in recovery model of patients undergoing open kidney surgery under general anesthesia

Public title

Comparison BIS Monitoring with Clinical Monitoring in recovery model of patients undergoing open kidney surgery under general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion: all patients underwent kidney open surgery. Exclusion criteria: personality or neurological

disorders; history of head trauma; drug abuse; use of drugs that affect the CNS; skull or frontal abnormalities; uncontrolled hypertension (SBP>160 or DBP>105); SBP<90; HR<55; Diabetes mellitus; BMI>33; emergency surgeries; ASA class ≥ II.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Shahid Beheshti Freeway

City
Rasht

Postal code
4193833697

Approval date
2015-03-17, 1393/12/26

Ethics committee reference number
1930003509

Health conditions studied

1

Description of health condition studied
Kidney open surgery

ICD-10 code
N19

ICD-10 code description
Unspecified kidney failure

Primary outcomes

1

Description
The eye opening time

Timepoint
At the time of recovery

Method of measurement
According to report of resident of anesthesiology

2

Description
The time of oral response to verbal stimuli

Timepoint
At the time of recovery

Method of measurement
According to report of resident of anesthesiology

3

Description
Extubation time

Timepoint
At the time of recovery

Method of measurement
According to report of resident of anesthesiology

4

Description
Stay in recovery time

Timepoint
At the time of recovery

Method of measurement
According to records

5

Description
Patient's VAS in recovery unit

Timepoint
At the time of recovery unit

Method of measurement
According VAS score

6

Description
The total amount of narcotic injecting

Timepoint
During and after surgery

Method of measurement
According to records

7

Description
The first time of injection of narcotic after surgery

Timepoint
At the time of recovery unit

Method of measurement

According to records

Secondary outcomes

empty

Intervention groups

1

Description
Checking depth of anesthesia measure by checking the heart rate, blood pressure, tears, sweat and pupil size
Category
Diagnosis

2

Description
Checking depth of anesthesia using BSI monitoring
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Hossein khoshrang
Street address
razi Street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Guilan 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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Person responsible for updating data

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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