

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Remifentanil - Propofol versus Fentanyl - Propofol on Urine Output in patients undergoing elective surgery of Posterior Spinal Fixation to General Anesthesia the method Total Intravenous Anesthesia

Protocol summary

Summary

The purpose of this study was to determine the Comparison of Remifentanil - Propofol versus Fentanyl - Propofol on Urine Output in patients undergoing elective surgery of Posterior Spinal Fixation to General Anesthesia. 60 patients in a double-blind clinical trial with random sampling method with Inclusion criteria, including; Elective surgery of Posterior Spinal Fixation; Age range 18-75 years and American Society of Anesthesiologists 1 and 2, and also Exclusion criteria, which include; Lack of patient satisfaction, Under 18 years and more than 75 years, Renal Disease, Uncontrolled Hypertension and Diabetes, Severe Cardiovascular Disease, Hypotension continuously during surgery, Use of medications and drugs affecting renal function both before and during anesthesia, Uncontrollable bleeding during surgery, Anyone who Hospitals affiliated to Tehran University of Medical Sciences in the years 1389-1390 are presented, and selected two groups 30 persons Remifentanil -Propofol and Fentanyl - Propofol we divided .Both groups received the drug in terms of drug Premedication and the Induction are equally. and Remifentanil & Propofol & Atracurium Maintenance drug in the Target Group and the Control Group included Fentanyl & Propofol & Atracurium. Then demographic characteristics of patients before the anesthesia record. And also Urine Output during anesthesia and the patient's Vital signs every half hour, we recorded and measured.

General information

Acronym

PSF(Posterior Spinal Fixation)

IRCT registration information

IRCT registration number: **IRCT201111298083N2**

Registration date: **2012-02-11, 1390/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-11, 1390/11/22

Registrant information

Name

Kayvan Latifi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 911 391 8734

Email address

k-latifi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2010-09-26, 1389/07/04

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Remifentanil - Propofol versus Fentanyl - Propofol on Urine Output in patients undergoing elective

surgery of Posterior Spinal Fixation to General Anesthesia
the method Total Intravenous Anesthesia

Public title
Remifentanyl effect on Urinary Output

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Elective surgery of Posterior Spinal Fixation; Age range 18-75 years; Operation length $\geq$ 3 hours; ASA 1-2; Normotention. Exclusion criteria: Lack of patient satisfaction; Age < 18 and Age > 75; Operation length < 3 hours; Kidney Disorders; Blood urea and Creatinine above the normal range of (BUN > 20 and Cr > 1.5); ASA > 2; Uncontrolled Hypertension and DM; Severe Cardiovascular Disease; Failure to observe during fasting (8 hours); Medications of plant installation and material effect on kidney function both before and during anesthesia(eg: Aminoglycosides - Magnesium Sulfate - Radiographic Contrast Agents - some heart medications and blood pressure reduction...); Patients Addicted to Narcotics; Hypotension continuously during Surgery (Systolic Pressure less than 80mmHg); Noncompliance of fluid intake during Anesthesia; Bleeding uncontrolled during Surgery; The use of PEEP in the Anesthesia; emergency surgery; Dehydration before Surgery

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Fakhre Razi st.

City

Tehran

Postal code

Approval date
2010-09-25, 1389/07/03

Ethics committee reference number
42118

Health conditions studied

1

Description of health condition studied
Lumbosacral Trauma

ICD-10 code
M99

ICD-10 code description
Biomechanical lesions, not elsewhere classified

Primary outcomes

1

Description
Urinary Output

Timepoint
Every 30 minutes during Anesthesia

Method of measurement
In terms of cc by Urine Bags

2

Description
Age

Timepoint
Before Anesthesia

Method of measurement
According to Years by ID

3

Description
Sex

Timepoint
Before Anesthesia

Method of measurement
Male or Female

4

Description
Weight

Timepoint
Before Anesthesia

Method of measurement
Kilogram By the Scale

5

Description
ASA

Timepoint
Before Anesthesia

Method of measurement

I & II

6

Description

Past Medical History

Timepoint

Before Anesthesia

Method of measurement

Medical History and Patient Medical Records

7

Description

Drug History

Timepoint

During Anesthesia

Method of measurement

micro/kg/min

8

Description

Blood Pressure

Timepoint

Every 30 minutes during Anesthesia

Method of measurement

In terme of milimetre Hg by Arterial Line

9

Description

Pulse Rate

Timepoint

Every 30 minutes during Anesthesia

Method of measurement

ECG Monitoring

Secondary outcomes

1

Description

Hypotention

Timepoint

During Anesthesia

Method of measurement

mmGh by Arterial Line

2

Description

Beradicardia

Timepoint

During Anesthesia

Method of measurement

Pulse/min by ECG

Intervention groups

1

Description

Intervention group: Remifentanyl, 2\0 micro/kg/min ,
Infusion to the onset of anesthesia , Propofol : 100 micro/
kg / min ,Infusion to the onset of anesthesia

Category

Treatment - Drugs

2

Description

Control group: Fentanyl, 5\0 - 5 micro/kg / hr , The bluse
during anesthesia , Propofol : 100 micro/ kg / min ,The
infusion during anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrateh Rasul Akram Hospital

Full name of responsible person

Dr. Kayvan Latifi

Street address

Hazrateh Rasul Hospital, Niayesh Street, Satarkhan
Street

City

Tehran

2

Recruitment center

Name of recruitment center

Firozgar Hospital

Full name of responsible person

Dr.Kayvan Latifi

Street address

Valadi Street , Valiasr Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Chancellor for research of University

Street address

Room 303, First Floor, Official Building (A), School of
Medicine

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor
organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Kayvan Latifi

Position

Dr. Anesthesia Assistant

Other areas of specialty/work

Street address

Hazrateh Rasul Hospital, Niayesh Street, Satarkhan Street

City

Tehran

Postal code

Phone

+98 19 2262 6212

Fax

Email

latifikayvan@gmail.comlatifikayvan@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Valiolla Hassani

Position

Dr./Tehran University Professor and Member of Board of Anesthesiology

Other areas of specialty/work

Street address

Anesthesia Group, Hazrateh Rasul Hospital, Niayesh Street, Satarkhan Street

City

Tehran

Postal code

Phone

+98 21 6650 9059

Fax

Email

v-hassani@sina.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kayvan Latifi

Position

Dr. / Anesthesia Assistant

Other areas of specialty/work

Street address

Anesthesia Group, Hazrateh Rasul Hospital, Niayesh Street, Satarkhan Street

City

Tehran

Postal code

Phone

+98 21 6650 9059

Fax

Email

latifikayvan@gmail.comlatifikayvan@yahoo.com

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