

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

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Name of organization / entity

Tehran University of Medical Sciences

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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		Tehran
Public title	Remifentanyl effect on Urinary Output	Postal code
Purpose	Prevention	Approval date 2010-09-25, 1389/07/03
Inclusion/Exclusion criteria	Inclusion criteria: Elective surgery of Posterior Spinal Fixation; Age range 18-75 years; Operation length ≥ 3 hours; ASA 1-2; Normotension. 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	Ethics committee reference number 42118
Age	From 18 years old to 75 years old	Health conditions studied
Gender	Both	1
Phase	N/A	Description of health condition studied Lumbosacral Trauma
Groups that have been masked	No information	ICD-10 code M99
Sample size	Target sample size: 60	ICD-10 code description Biomechanical lesions, not elsewhere classified
Randomization (investigator's opinion)	Randomized	Primary outcomes
Randomization description		1
Blinding (investigator's opinion)	Double blinded	Description Urinary Output
Blinding description		Timepoint Every 30 minutes during Anesthesia
Placebo	Not used	Method of measurement In terms of cc by Urine Bags
Assignment	Parallel	2
Other design features		Description Age
Secondary Ids	empty	Timepoint Before Anesthesia
Ethics committees		Method of measurement According to Years by ID
1		3
Ethics committee		Description Sex
Name of ethics committee	Tehran University of Medical Sciences	Timepoint Before Anesthesia
Street address	Fakhre Razi st.	Method of measurement Male or Female
City		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**

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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