

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the characteristics of patients treated with and without Propofol in the intensive care unit of MasihDaneshvari Hospital.

Protocol summary

Study aim

Evaluation the effects and risks of using propofol in patients admitted to the intensive care unit of Masih Daneshvari Hospital.

Design

Patients' information in the first three years of this study is related to the cases that treated with propofol & in the next eight years, it is related to patients that Propofol has not been used in the treatment. A random selection of patients were performed from both groups. Their data were recorded from their records and compared to demographic characteristics and variables such as: cardiac output, hypertension, hyperlipidemia, sepsis.

Settings and conduct

This study conducted in surgical Intensive Care Unit in Masih Daneshvari Hospital, Tehran, Iran. Patients' information in the first three years of this study is related to the cases that treated with propofol & In the next eight years, it is related to patients that Propofol has not been used in the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients need a sedative in the intensive care unit. Exclusion criteria: patients with propofol sensitivity; patients with certain underlying conditions

Intervention groups

Patients treated with propofol and without propofol

Main outcome variables

Evaluate the effects and risks of using propofol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N19**

Registration date: **2018-07-29, 1397/05/07**

Registration timing: **retrospective**

Last update: **2018-07-29, 1397/05/07**

Update count: **0**

Registration date

2018-07-29, 1397/05/07

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the characteristics of patients treated with and without Propofol in the intensive care unit of MasihDaneshvari Hospital.

Public title

Comparison of the characteristics of patients treated with and without Propofol

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients need a sedative in the intensive care unit

Exclusion criteria:

Patients with propofol sensitivity Patients with certain underlying conditions

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **500**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Masih Daneshvari Hospital the Educational ,
Research and Treatment center.

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

IR.SBMU.MSP.REC.1396.747

Health conditions studied**1****Description of health condition studied**

Patients treated with and without Propofol in the intensive care unit.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Evaluate the effects and risks of using propofol.

Timepoint

After using propofol

Method of measurement

The checklist includes demographic features and variables such as cardiac output, hypotension, hyperlipidemia, and sepsis.

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Before and after the intervention.

Method of measurement

Barometer

2**Description**

Cardiac Output

Timepoint

Before and after intervention

Method of measurement

monitoring

Intervention groups**1****Description**

Intervention group: treated with Propofol 10%. The drug that is used as a short intravenous injection method and it reduces the level of consciousness or anesthesia. For adult patients, it is advisable to use low doses for intravenous infusion and, after ensuring the stability of the hemodynamic, the dose was increased. In this study, 2.5 mg / kg anesthetic dose of propofol was induced and propofol was used for prolonged relief of 0.1 mg / kg / min.

Category

Treatment - Drugs

2**Description**

Control group: Treated without Propofol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Edjucational , Research and Treatment center

Full name of responsible person

Dr Seyyed Mohammad Reza Hashemian

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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

The Edjucational , Research and Treatment center

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

The Edjucational , Research and Treatment center

Full name of responsible person

Seyyed Mohammad Reza Hashemian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Seyyed Mohamad Reza Hashemian

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Somayeh Aakhavan

Position

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Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available