

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the influence of intraoperative Remifentanil and Fentanyl on postoperative pain following adult orthotopic liver transplant surgery: A randomized clinical trial

Protocol summary

Study aim

Comparison between the influence of intraoperative Remifentanil and Fentanyl on postoperative pain following adult orthotopic liver transplant surgery

Design

Two arm parallel group of 64 patients, randomized clinical trial, double blinded, randomization performed by random-numbers table.

Settings and conduct

The patients will be grouped by numeric coding. The patient will not be aware of the type of administered drug. The chief researcher who is responsible for patient's safety and preparing the drugs will be aware of the drug administered. But the resident and the nurse in the operating room will not know which drug is given to the patient. The researcher (responsible anesthesiologist) will prepare two syringes with the same volume and the same appearance (clear fluid in 50 cc-syringe) and these syringes will be given to the nurse/resident in the operating room. The duration of infusion will be the same for both groups. Groups coding is numerical and the intensive care unit personnel and the epidemiologist responsible for analysis of the data

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 65 years old; candidate for orthotopic liver transplant surgery in Taleghani Hospital; no previous history of opioids abuse
Exclusion criteria: Lack of consent from the patient for study enrollment

Intervention groups

Fentanyl group: prescribed Fentanyl infusion during surgery
Remifentanyl group: prescribed Remifentanyl infusion during surgery

Main outcome variables

Amount of postoperative analgesic medications during the first 72 hours after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151012024493N6**

Registration date: **2023-02-24, 1401/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-24, 1401/12/05**

Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Parissa Sezari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 219 4036

Email address

psezari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	infusion will be the same for both groups. Groups coding is numerical and the intensive care unit personnel and the epidemiologist responsible for analysis of the data will not be aware of coding type.
Scientific title Comparison between the influence of intraoperative Remifentanyl and Fentanyl on postoperative pain following adult orthotopic liver transplant surgery: A randomized clinical trial	Placebo Not used
Public title comparing fentanyl and remifentanyl in liver transplant surgery	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Age between 18 to 65 years old Candidate for orthotopic liver transplant surgery in Taleghani Hospital No previous history of opioids abuse Exclusion criteria: Lack of consent from the patient for study enrollment	Secondary Ids empty
Age From 18 years old to 65 years old	Ethics committees <u>1</u>
Gender Both	Ethics committee Name of ethics committee Vice-Chancellor in Research Affairs-Shahid Beheshti University of Medical Sciences
Phase 2-3	Street address Shahid Beheshti University of Medical Sciences, Koudakyar st., Daneshgah Sq., Velenjak, Tehran, Iran
Groups that have been masked • Participant • Outcome assessor • Data analyser	City تهران
Sample size Target sample size: 32	Province Tehran
Randomization (investigator's opinion) Randomized	Postal code 1985717443
Randomization description Random-number table In this study, people enter the study groups by lottery; In such a way that the type of injectable drug used is placed in the desired number in the sealed opaque envelopes that are coded. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes out one of the pieces of paper from the box. The envelope has the same number as the number inside the selected paper. which is applied to the patient. This work continues until the end of the papers so that the number of patients reaches the desired number in the groups.	Approval date 2022-12-04, 1401/09/13
Blinding (investigator's opinion) Triple blinded	Ethics committee reference number IR.SBMU.MSP.REC.1401.477
Blinding description The patients will be grouped by numeric coding. The patient will not be aware of the type of administered drug. The chief researcher who is responsible for patient's safety and preparing the drugs will be aware of the drug administered. But the resident and the nurse in the operating room will not know which drug is given to the patient. The researcher (responsible anesthesiologist) will prepare two syringes with the same volume and the same appearance (clear fluid in 50 cc-syringe) and these syringes will be given to the nurse/resident in the operating room. The duration of	Health conditions studied <u>1</u> Description of health condition studied Liver Transplantation
	ICD-10 code ICD-10 code description
	Primary outcomes <u>1</u> Description Amount of postoperative analgesic medications
	Timepoint 72 hours after surgery
	Method of measurement Calculating the total dose of given analgesics by nursing chart
	Secondary outcomes empty

Intervention groups

1

Description

Intervention group: In Fentanyl group, Fentanyl is infused by the rate of 0.03-1 mcgr/Kg body weight/min during surgery.

Category

Treatment - Drugs

2

Description

Intervention group: In Remifentanyl group, Fentanyl is infused by the rate of 0.03-1 mcgr/Kg body weight/min during surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Soodeh Tabashi

Street address

Shahid A'rabi St., Yaman St. , Shahid Chamran Highway

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1985711151

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taleghani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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info@sbmu.ac.ir

Web page address

<https://en.sbmu.ac.ir/index.jsp?siteid=256&fkeyid=&siteid=73&pageid=13079>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more data is 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

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant professor

Latest degree

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