

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation and comparison of the preconditioning effect of Remifentanyl Vs. Fentanyl on prevalence of early graft dysfunction among patients with liver transplant

Protocol summary

Study aim

To evaluate the preconditioning of remifentanyl Vs. fentanyl in prevalence of early graft dysfunction in liver transplant patients

Design

Parallel triple blinded clinical trial

Settings and conduct

100 patients who underwent liver transplantation in the Namazi hospital were randomly allocated into two groups of remifentanyl and fentanyl and after surgery, all patients were routinely transferred to intensive transplant care unit. Biopsy was done for all the donors' livers to evaluate the percentage of macro vesicular stenosis.

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: patients aged 18 to 65 years old and patients with history of hepatopulmonary syndrome; portopulmonary hypertension; renal insufficiency (Cr > 1.5 mg/L). **EXCLUSION CRITERIA:** allergy to propofol soy beans and egg; donors with cardio-pulmonary arrest or hemodynamic instability with high doses of inotropes (infusion norepinephrine above $\mu\text{g}/\text{min}$) and cold ischemia time more than 12 hours.

Intervention groups

Remifentanyl group: patients received intravenous propofol infusion with doses of 100-150 $\mu\text{g}/\text{kg}/\text{min}$ as a base of maintenance of anesthesia and remifentanyl $\mu\text{g}/\text{kg}/\text{min}$ 0.1-0.4 infusion (syringe B remifentanyl with dilution 40 $\mu\text{g}/\text{cc}$). Fentanyl group: patients received intravenous propofol infusion with doses of 100-150 $\mu\text{g}/\text{kg}/\text{min}$ as a base of maintenance of anesthesia with $\mu\text{g}/\text{kg}/\text{min}$ 0.03-0.1 fentanyl infusion during maintenance of anesthesia (syringe B, fentanyl with dilution 50 $\mu\text{g}/\text{cc}$).

Main outcome variables

Aspartate transaminase (AST), Alanine transaminase (ALT), Alkaline phosphatase (Alkp), prothrombin time (PT), partial thrombin time (PTT) and international

normalized ratio (INR) from day 1 to 7 post-operation will be assessed. blood urea nitrogen (BUN), creatinine (Cr), and metabolic acidosis (PH, base excess (BE)). These were evaluated from day 1 to 7 post-operation. Duration of hospital and ICU stay, ventilator need and extubation time post-operation, cold and warm ischemia time and the received blood products during the operation were recorded

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N70**

Registration date: **2018-02-19, 1396/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-07, 1397/01/18**

Update count: **1**

Registration date

2018-02-19, 1396/11/30

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2018-02-15, 1396/11/26

Expected recruitment end date

2018-08-17, 1397/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the preconditioning effect of Remifentanyl Vs. Fentanyl on prevalence of early graft dysfunction among patients with liver transplant

Public title

Evaluation and comparison of the preconditioning effect of Remifentanyl Vs. Fentanyl on prevalence of early graft dysfunction among patients with liver transplant

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

aged 18 to 65 years old patients who are candidate for liver transplant

Exclusion criteria:

allergy to propofol soy beans and egg donors with cardio-pulmonary arrest or hemodynamic instability with high doses of inotropes (infusion nor epinephrine above µg/min) cold ischemia time more than 12 hours. history of hepatopulmonary syndrome history of portopulmonary hypertension renal insufficiency (Cr > 1.5 mg/L)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized according to the charts which was derived from www.randomization.org site.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind: participants and assessors of the outcomes are unaware of the study groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2016-09-10, 1395/06/20

Ethics committee reference number

IR.SUMS.MED.REC.1395.38

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

organ transplant

ICD-10 code

Y83.0

ICD-10 code description

Surgical operation with transplant of whole organ

Primary outcomes**1****Description**

Aspartate transaminase (AST), Alanine transaminase (ALT), Alkaline phosphatase (Alkp), prothrombin time (PT), partial thrombin time (PTT) international normalized ratio (INR)

Timepoint

from day 1 to 7 post-operation

Method of measurement

blood sample

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

Blood urea nitrogen (BUN)

Timepoint

From day 1 to 7 post-operation

Method of measurement

Blood sample

2

Description

Duration of hospital and ICU stay

Timepoint

From day 1 to the day of discharge

Method of measurement

Observation

3

Description

Metabolic acidosis (PH, base excess (BE)

Timepoint

From day 1 to 7 post-operation

Method of measurement

Blood sample

4

Description

Creatinine (Cr)

Timepoint

From day 1 to 7 post-operation

Method of measurement

Blood sample

5

Description

Duration of mechanical ventilation

Timepoint

From day 1 to 7 post-operation

Method of measurement

Observation

6

Description

Extubation time post- operation

Timepoint

From day 1 to 7 post-operation

Method of measurement

Observation

7

Description

Cold and warm ischemia time

Timepoint

Intra-operative

Method of measurement

Observation

8

Description

Amount of received blood products during the operation

Timepoint

Intra-operative

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: In the remifentanil group, patients received intravenous propofol infusion with doses of 100-150 µg/kg/min as a base of maintenance of anaesthesia and remifentanil µg/kg/min 0.1-0.4 infusion (syringe B remifentanil with dilution 40 µg/cc).

Category

Prevention

2

Description

Intervention group: in fentanil group patients received intravenous propofol infusion with doses of 100-150 µg/kg/min as a base of maintenance of anesthesia with µg/kg/min 0.03-0.1 fentanil infusion during maintenance of anesthesia (syringe B, fentanil with dilution 50 µg/cc).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hosptioal

Full name of responsible person

Sanaz Jowkar

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Namazi Hoptioal, Namazi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Sanaz Jowkar

Position
Anesthesiology Resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Latest degree
Master

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

Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report

Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable