Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

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

Protocol summary

Study aim

To evaluate the preconditioning of remifentanil Vs. fentanil 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 remifentanil and fentanil 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 µg/min) and cold ischemia time more than 12 hours.

Intervention groups

Remifentanil group: patients received intravenous propofol infusion with doses of 100-150 µg/kg/min as a base of maintenance of anesthesia and remifentanil µg/kg/min 0.1-0.4 infusion (syringe B remifentanil with dilution 40 µg/cc). Fentanil group :patients received intravenous propofol infusion with doses of 100-150 µg/kg/min as a base of maintenance of anesthesia withµg/kg/min 0.03-0.1 fentanil infusion during maintenance of anesthesia (syringe B, fentanil with dilution 50 µg/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

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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 Remifentanil Vs. Fentanyl on prevalence of early graft dysfunction among patients with liver transplant

Public title
Evaluation and comparison of the preconditioning effect of Remifentanil 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 dicharge
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 withµg/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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
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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
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Person responsible for updating data

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MS in English Teaching ,BS in anesthesia/English Consultant
Latest degree
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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