# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the efficacy of two different antibiotic prophylactic regimens for bacterial infections in liver transplant recipients

### Protocol summary

**Study aim**
The purpose of this study is to compare the efficacy of two different antibiotic prophylactic regimens for bacterial infections in liver transplant recipients.

**Design**
single-blinded randomized clinical trial which included 182 candidates for liver transplantation,"simple randomization" method will be use to divide the patients into two groups.

**Settings and conduct**
All patients will be divided into two groups after randomization. The first group will receive Ampicillin-Sulbactam (3 g every 6 hours) with Ceftizoxime (2 g every 8 hours) and the second group will receive Ampicillin - Sulbactam (3 g every 6 hours) with Gentamicin (5 mg/kg/day intravenously once daily ) for 48 hours. All patients will be followed for bacterial infections for one month after liver transplantation. This study will be done at Bou Ali Sina hospital which affiliated to Shiraz University of Medical Sciences, Shiraz, Iran.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: all patients who are candidates for liver transplantation. Exclusion criteria: patients with known renal failure or require dialysis, and also any prior history of allergic drug reactions to one of the antibiotics used in this study.

**Intervention groups**
Patients were randomly assigned in two groups receiving Ampicillin-Sulbactam (3 g every 6 hours) with Ceftizoxime (2 g every 8 hours) or Ampicillin - Sulbactam (3 g every 6 hours) with Gentamicin (5 mg/ kg/day intravenously once daily )for 48 hours. All medications adjusted according to renal function.

**Main outcome variables**
Primary outcomes included: Length of hospital stay,mortality rate during the study period, the pattern of sensitivity and resistance of all pathogens isolated from patients with positive culture and type and number of them, any clinical or laboratory manifestation suggests bacterial infections

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120731010453N2**
Registration date: **2018-11-09, 1397/08/18**
Registration timing: **prospective**

Last update: **2018-11-09, 1397/08/18**
Update count: **0**

**Registration date**
2018-11-09, 1397/08/18

**Registrant information**

**Name**
Mojtaba Shafiekhani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 3242 4255

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-11-21, 1397/08/30

**Expected recruitment end date**
2019-03-21, 1398/01/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Comparison of the efficacy of two different antibiotic prophylactic regimens for bacterial infections in liver transplant recipients

**Public title**
Efficacy of two different antibiotic prophylactic regimens in liver transplant recipients

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
All patients which candidate to liver transplant older than 18 years old

**Exclusion criteria:**
Positive history of allergic reactions to antibiotics which use in this study renal failure patients with hemo-dialysis serum creatinine levels more than 1.5 mg/dL,blood urea nitrogen (BUN) more than 25 mg/dL

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Care provider

**Sample size**
Target sample size: **182**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Before the beginning of liver transplant surgery, all eligible patients were divided into two intervention and control groups by operating room technician using the random numbers table that was at his disposal.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
In our study, liver transplant surgeons do not know the patients took which of antibiotic prophylactic regimens before surgery

**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**
Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

**City**
Shiraz

**Province**
Fars

**Postal code**
71348-14336

**Approval date**
2018-09-30, 1397/07/08

**Ethics committee reference number**
IR.SUMS.REC.1397.644

## Health conditions studied

### 1

**Description of health condition studied**
liver transplantation

**ICD-10 code**
T86.43

**ICD-10 code description**
Liver transplant infection

## Primary outcomes

### 1

**Description**
Incidence of bacterial infections in the first month after liver transplantation

**Timepoint**
During first month after liver transplantation

**Method of measurement**
Centers for Disease Control and Prevention (CDC) definitions for nosocomial infections.

## Secondary outcomes

### 1

**Description**
mortality rate in liver transplant patients

**Timepoint**
Duration of hospitalization

**Method of measurement**
By reviewing patient file information

### 2

**Description**
Length of intensive care unit stay

**Timepoint**
Duration of hospitalization

**Method of measurement**
By reviewing patient file information

### 3

**Description**

Length of hospital stay

**Timepoint**

Duration of hospitalization

**Method of measurement**

By reviewing patient file information

## Intervention groups

### 1

**Description**

first Intervention group: Ampicillin-sulbactam(3 g every 6 hours) with Ceftizoxime (2 g every 8 hours)

**Category**

Treatment - Drugs

### 2

**Description**

Second Intervention group: Ampicillin-sulbactam(3 g every 6 hours) with Gentamicin (5 mg/Kg.once daily)

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Abu Ali Sina Organ Transplant hospital

**Full name of responsible person**

Mojtaba Shafiekhani

**Street address**

Abu Ali Sina Organ Transplant, Sadra Highway

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

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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**

Mojtaba Shafiekhani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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