Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 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)

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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

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Abu Ali Sina Organ Transplant, Sadra Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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