Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The role of ganciclovir in the prevention of Post-transplant lymph proliferative disease in children underwent liver transplantation

Protocol summary

Summary

1 . Objectives: Gansiklovir prophylaxis in the prevention of post- transplant lymphoproliferative disease , ¬ 2. Design of non- blind , single- center , phase 3 clinical trial 3. Participants in the study inclusion criteria : age less than 18 years ;performing a liver transplant exclusion criteria : transplant before July 88 and after March 90; die within the first week after transplantation due to postoperative complications 4 . the sample size : 203 patients 5. way to intervention group children who underwent liver transplantation were enrolled and received prophylaxis Gansyklvvyr . Control group of children who had undergone liver transplantation but did not receive Gansiclovir 6. Intervention : a month 7 . Changing the primary outcome : prevention of lymphoproliferative disorders

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120215530N2**
Registration date: **2014-01-31, 1392/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-01-31, 1392/11/11

Registrant information

Name
Karamali Kasiri
Name of organization / entity
Shahrekord University of Medical sciences.
Country
Iran (Islamic Republic of)
Phone
+98 38 1222 0016
Email address
kasiri@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences.

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of ganciclovir in the prevention of Post-transplant lymph proliferative disease in children underwent liver transplantation

Public title

role of ganciclovir in the prevention of Post-transplant lymph proliferative disease in children underwent liver transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age less than 18 years; performing a liver transplant Exclusion criteria: transplant before July 88 and after March 90; die within the first week after transplantation due to postoperative complications

Age

To **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **203**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Shiraz Medical university of sciences

Street address

Shiraz Medical university of sciences

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

59-30-90

Health conditions studied

1

Description of health condition studied

Transplanted organ and tissue status

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes

1

Description

prevention of Post-transplant lymph proliferative disease

Timepoint

A month later

Method of measurement

examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: children who underwent a liver transplant in January 2010 to the end of 2011 received prophylaxis Gansiclovir10mg/kg,Two divided doses.

Category

Treatment - Drugs

2

Description

Control group:children who had undergone liver transplantation but did not receive Gansiklovir.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital Shiraz

Full name of responsible person

Karamali Kasiri

Street address

Shiraz،Zand Street ،the prayer Square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research,Shiraz University of Medical Sciences

Full name of responsible person

Vice Chancellor for research,Shiraz University of Medical l Sciences

Street address

Vice Chancellor for research,Shiraz University of Medical ,Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research,Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medica Sciences.

Full name of responsible person

karamali kasiri

Position

Pediatric gastroenterologist.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty