

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 Gansyklvyr . 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

+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

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

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 I 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 Medical Sciences.

Full name of responsible person

karamali kasiri

Position

Pediatric gastroenterologist.

Other areas of specialty/work

Street address

Rahmatie, Shahrekord University of Medical Sciences,
Shahrekord

City

Shahrekord

Postal code

Phone

+98 38 1222 0016

Fax

Email

kasiri@skums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences.

Full name of responsible person

Karamali Kasiri

Position

Pediatric gastroenterologist, Assistant Professor

Other areas of specialty/work

Street address

Rahmatie, Shahrekord University of Medical Sciences,
Shahrekord

City

Shahrekord

Postal code

Phone

+98 38 1333 5652

Fax

Email

kasiri@skums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences.

Full name of responsible person

Karamali Kasiri

Position

Pediatric gastroenterologist, Assistant Professor

Other areas of specialty/work

Street address

Rahmatie, Shahrekord University of Medical Sciences,
Shahrekord

City

Shahrekord

Postal code

Phone

+98 38 1222 0016

Fax

Email

kasiri@skums.ac.ir

Web page address

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