

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of comparision of 3and 6 months prophylaxis with valganciclovir for prevention of cytomegalovirus(CMV) disease in children with renal transplantation

Protocol summary

Summary

This study is a clinical trial for comparison the effect of 3 and 6 months prophylaxis with valganciclovir drug for prevention of cytomegalovirus (CMV) infection in children with renal transplantation. This study is single blind, and the sample population consists of 86 children that have renal transplantation and also receive organs from people who are positive of CMV infection. Thus children that receive organs from negative donors are excluded. The use of Thymoglobuline drug is a important exclusion criteria in this study. We use simple random method in Rasool-Akram and Ali-Asghar hospitals for sampling. By random method, we give the half of the children valganciclovir drug for 3 months and the another half of the children for 6 months by 10-15 mg/kg daily. After that, we follow these children for a year after transplantation(9 months after 3 months prophylaxis and 6 months after 6 months prophylaxis), and do monthly experiments in both groups to compare the incident rate of CMV infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021321062N1**

Registration date: **2015-05-12, 1394/02/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-12, 1394/02/22

Registrant information

Name

Niloofar Khosravi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Iran
University of Medical Sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparision of 3and 6 months prophylaxis with valganciclovir for prevention of cytomegalovirus(CMV) disease in children with renal transplantation

Public title

The effect of duration of treatment with valganciclovir in children with renal transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The children who receive organs from people who are CMV positive; The children are 1-14

years-old Exclusion criteria: The use of Thymoglobuline drug; The children who are effected severely by side effects of valganciclovir drug; for example: severe leukopenia or anemia

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran university of medical sciences

Street address

Iran University of Medical Sciences, between Hemmat highway and Sheykh Fazlolah highway

City

Tehran

Postal code

Approval date

2015-02-15, 1393/11/26

Ethics committee reference number

93-03-30-25001-109010

Health conditions studied

1

Description of health condition studied

renal failure

ICD-10 code

N17

ICD-10 code description

Acute renal failure

2

Description of health condition studied

CMV infection

ICD-10 code

B99

ICD-10 code description

Other and unspecified infectious diseases

Primary outcomes

1

Description

CMV infection

Timepoint

before intervention, 15 days after intervention, every month until 1 year after intervention

Method of measurement

Laboratory methods of Qualitit PCR and PP65

Secondary outcomes

1

Description

side effects of valganciclovir drug like: Anemia and Allergic hypersensitivity

Timepoint

every month after intervention until 1 year

Method of measurement

clinical presentation

Intervention groups

1

Description

control group: treatment with Valganciclovir, 10-15 mg per kg for everyone, daily, for 3 months

Category

Treatment - Drugs

2

Description

intervention group: treatment with valganciclovir, 10-15 mg per kg for everyone, daily, for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Asghar Children Hospital

Full name of responsible person

Dr Rozita Hoseini

Street address

Ali-Asghar Children Hospital, Shahid Vahid Dastgerdi

street, Modarres highway

City

Tehran

2

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Dr Nahid Rahim-Zadeh

Street address

Rasool Akram Hospital, Niyayesh street, Sattar-Khan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Mehrdad Eftekhari

Street address

Iran University of Medical Sciences, Hemmat highway

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Ali-Asghar Hospital

Full name of responsible person

Nilooofar Khosravi

Position

Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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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