Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the efficacy and safety of Oral Sirolimus and oral cyclosporine in the chronic thrombocytopenic purpura immune in children

Protocol summary

Study aim

1.The Effects of cyclosporine and Sirolimus on improving symptoms of patients with idiopathic thrombocytopenic purpura (ITP) will be compared. 2.The incidence of complications of cyclosporine and oral Sirolimus in patients with idiopathic thrombocytopenic purpura (ITP) will be compared.

Design

A clinical trial including two groups receiving oral cyclosporine and sirolimus, with parallel groups, single blind, randomized

Settings and conduct

this study is grounded in the field of idiopathic thrombocytopenic purpura in Arak city. After getting informed consent from the parents, demographic information will be recorded and patients will be divided into two groups receiving cyclosporine and Sirolimus(for 6 months) randomly. The response rate in patients is an increase in platelet count, which is measured monthly.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1.Children aged 5 to 15 years with chronic idiopathic thrombocytopenic purpura 2.Not having any other blood diseases 3.Parental informed consent exclusion criteria : 1.Increase BUN / CR or decrease GFR by less than 50 ml / day. 2.Seizure 3.Allergic reaction 4.Oral drug intolerance 5.no response to drug treatment after 3 months.

Intervention groups

The control group received 5 mg / kg of cyclosporine twice a day The Intervention group (received oral Sirolimus), on the first day, will received Sirolimus in loading dose 6 mg / m2/day(in children above 40 kg) and 3mg/m2/day(children less than 40 kg). From the second day, children over 40 kg will receive 2 mg/m2 /day and under 40 kg will receive 1 mg/kg/day of Sirolimus.The control group consists of the same number of patients with the treatment groups which does not receive the two above drugs. Treatments will be received for 6 months.

Main outcome variables

Increase platelet count

General information

Reason for update

Given that the initial registration was not properly entered due to the importer's inexperience. The following require editing : 1. The sampling in the study was done after receiving IRCT code, but in the initial record, the sampling was entered before receiving the code, which was corrected. 2. This study is a randomized single blind study, but in the initial registration it has mistakenly recorded as a non-random and one blind study. This problem was corrected too.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180501039499N1**
Registration date: **2018-08-12, 1397/05/21**
Registration timing: **prospective**

Last update: **2020-02-05, 1398/11/16**
Update count: **1**

Registration date

2018-08-12, 1397/05/21

Registrant information

Name
Morteza Mousavihasanzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-10-17, 1397/07/25
Expected recruitment end date
2019-04-14, 1398/01/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the efficacy and safety of Oral Sirolimus and oral cyclosporine in the chronic thrombocytopenic purpura immune in children

Public title
Comparison of the Effects of Oral Sirolimus and Oral Cyclosporine on the Thrombocytopenic Chronic Purpura
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 5 to 15 years with chronic idiopathic thrombocytopenic purpura Not having any other blood diseases Parental informed consent
Exclusion criteria:
Increase BUN / CR or decrease GFR by less than 50 ml / day. Seizure Allergic reaction Oral drug intolerance No response to drug treatment after 3 months.
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization was done using permuted blocks of four different block sizes 2,4,6,8; then study subjects were separated 1:1 to Cyclosporine and sirolimos groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
After obtaining informed consent, patients will be randomly assigned to one of the two treatment groups(sirolimus or cyclosporine) and patients will be unaware of the type of treatment group they are in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Amir kabir hospital, Khoram AVe, Arak Town
City
Arak
Province
Markazi
Postal code
38146-7-5999
Approval date
2018-07-07, 1397/04/16
Ethics committee reference number
IR.ARAKMU.REC.1397.064

Health conditions studied

1

Description of health condition studied
Idiopathic thrombocytopenic purpura
ICD-10 code
D69.3
ICD-10 code description
Immune thrombocytopenic purpura

Primary outcomes

1

Description
Idiopathic thrombocytopenic purpura
Timepoint
Platelet measurement at the beginning of the study, months 1 to 6 after treatment
Method of measurement
The number of platelets is measured by using the Cell counter sysmax device.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group will receive oral cyclosporine 5 mg / kg / day twice a day for 6 months
Category
Treatment - Drugs

2

Description
Intervention group: Receiving oral Sirolimus in this group is as follows, , the first day of the loading dose is 6 mg and from the second day, 2 mg per m2 of body weight per day (children over 40 kg) and or the first day of the loading dose is 3 mg and from the second day, 1 mg per m2 of body weight per day (children over 40 kg) for 6 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir kabir Hospital

Full name of responsible person
Morteza.mousavihasanzadeh

Street address
Amir kabir Hospital, Khoram AVe, Arak town

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Sponsors / Funding sources

1

Sponsor

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Morteza MousaviHasanzadeh

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Pediatrics

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Position
Associate Professor

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Informed consent
When the data will become available and for how long
2018/07/07
To whom data/document is available
It's free to the public
Under which criteria data/document could be used
It's free to the public
From where data/document is obtainable
Call
What processes are involved for a request to access data/document
48 hours after the call
Comments
48 hours after the call