

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of primary intravenous methyl prednisolone pulse treatment in the prevention of coronary artery abnormality in children with Kawasaki disease

Protocol summary

Study aim

The effect of initial treatment with intravenous corticosteroid pulse on the prevention of coronary artery abnormality in children with Kawasaki disease, possibility to replace steroid pulse as a cheap and inexpensive treatment rather than expensive medicine.

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

After explaining to their parents and obtaining informed consent for treatment with IVIG or methylprednisolone pulse, patients are randomly assigned to two groups: control group treatment with IVIG 2g / kg, aspirin and intervention group treatment with intravenous pulse of methyl prednisolone 30 mg / kg in three days and continue with oral prednisolone at a dose of 1 mg / kg for three days. Echocardiographer is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- age of 6 months to 5 years old 2- complete and incomplete Kawasaki disease definition according to AHA. Exclusion criteria: complicated cases (MAS), recurrent Kawasaki, previous coronary artery abnormality, congestive heart failure, chronic renal failure, prednisolone sensitization, active viral infection of zoster, or Exposure to varicella in the past 21 days if not immunized, injecting oral, intravenous or muscular corticosteroid current > 3 days in the last 7 days, history of severe reaction to the preparation of any human globulin product, registration in another study possible. It will affect the effects of treatment, effectiveness or follow-up.

Intervention groups

After entering the study, patients were randomly divided into two groups: IVIG 2g / kg, aspirin and 3-day intravenous pulse methyl prednisolone at a dose of 30mg

/ kg, and continued treatment with oral prednisolone 1mg / kg for 3 days.

Main outcome variables

fever duration, frequency of symptoms, mean CRP inflammatory factors, frequency of CAA, severity of CAA

General information

Reason for update

Modification of inclusion criteria. With the highest prevalence of coronary involvement below the age of six months, the minimum age of inclusion criteria changed from one year to six months.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181202041817N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-06, 1398/10/16**

Update count: **1**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

nahid aslani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2153

Email address

nahidaslani51@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of primary intravenous methyl prednisolone pulse treatment in the prevention of coronary artery abnormality in children with Kawasaki disease

Public title

The effect of corticosteroid on the treatment of Kawasaki

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Kawasaki disease definition according to American Heart Association (AHA): Complete Kawasaki disease : Fever for more than 5 days plus at least four of the following clinical signs : Bilateral conjunctival injection, Changes in the oropharyngeal mucous membranes, including one or more of injected and/or fissured lips, strawberry tongue, injected pharynx ,Changes in the peripheral extremities, including erythema and/or edema of the hands and feet (acute phase) or periungual desquamation (convalescent phase), Polymorphous rash, Cervical lymphadenopathy with at least one node >1.5 cm Incomplete Kawasaki : Fever for more than 5 days plus fewer than 4 of the principal clinical findings, and compatible laboratory or echocardiographic findings.

Exclusion criteria:

Complicated disease(Macrophage Activating Syndrome) Patients with frequent KD Patients with Coronary Artery Abnormality have already been approved Congestive Heart Failure Chronic renal failure Sensitization to Methyl Prednisolone or Prednisolone Active viral viral zoster infection; or exposure to Varicella in the past 21 days if not safe Injection of Oral, Intravenous or Muscular Corticosteroids> 3 days in the last 7 days History of severe reaction to the preparation of any human globulin product Registering in another study that may affect the effects of treatment, effectiveness, or follow-up.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a sealed envelope. Thirty envelopes containing the word of IVIG and thirty envelopes containing the word of methylprednisolone pulse are inserted into the box. , Based on which type of the envelope comes out , treatment is selected at random.

Blinding (investigator's opinion)

Single blinded

Blinding description

One permanent cardiologist performs all echocardiography, which does not have any information about the type of treatment

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Ethics Committee for Biomedical Research

Street address

Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62, Children's Medical Center

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2019-03-27, 1398/01/07

Ethics committee reference number

IR.TUMS.CHMC.REC.1398.008

Health conditions studied**1****Description of health condition studied**

Kawasaki disease

ICD-10 code

M30.3

ICD-10 code description

Mucocutaneous lymph node syndrome [Kawasaki]

Primary outcomes**1****Description**

Coronary Artery abnormality in the Kawasaki disease

Timepoint

Echocardiography is performed at least three times

(immediately at the beginning of the diagnosis, two weeks and two months after the onset of the disease).

Method of measurement

Echocardiography

2

Description

Reduction of Coronary Artery abnormality in the Kawasaki disease

Timepoint

Echocardiography is performed at least three times (immediately at the beginning of the diagnosis, two weeks and two months after the onset of the disease).

Method of measurement

Echocardiography

Secondary outcomes

1

Description

The severity of coronary artery disease

Timepoint

At least three times (immediately at the start of the diagnosis, two weeks and two months after the onset of the disease)

Method of measurement

Echocardiography

2

Description

prevalence of coronary artery involvement

Timepoint

before intervention, 14 and 60 days after onset of treatment.

Method of measurement

echocardiography

Intervention groups

1

Description

Intervention group: Aspirin 30 mg / kg and intravenous methyl prednisolone pulse at 30 mg / kg in three days .Within 12 hours after the first dose of the steroid pulse, if the temperature return to normal and CRP drops to less than half before treatment, it is considered as response to treatment and treatment will continue with oral prednisolone at a dose of 1 mg / kg and if the temperature do not return to normal and CRP drops to less than half before treatment, it is considered as failure of treatment and will be treated with standard IVIG treatment similar to the control group.

Category

Treatment - Drugs

2

Description

Control group: Treatment with IVIG at 2g / kg and aspirin at 30 mg / kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Children's Medical Center Hospital

Full name of responsible person

Dr. Vahid Ziaee

Street address

Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62, Children's Medical Center

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 2153

Fax

+98 21 6693 0024

Email

ziaee@tums.ac.ir

Web page address

<http://chmc.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

دکتر وحید ضیایی

Street address

Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62, Children's Medical Center

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 2153

Fax

+98 21 6693 0024

Email

ziaee@tums.ac.ir

Web page address

<http://chmc.tums.ac.ir>

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Vahid Ziaee
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62,
Children's Medical Center
City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6659 5522
Fax
+98 21 6659 5525
Email
ziaee@tums.ac.ir
Web page address
<http://tums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Vahid Ziaee
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62,

Children's Medical Center
City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6659 5522
Fax
+98 21 6659 5525
Email
ziaee@tums.ac.ir
Web page address
<http://tums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Vahid Ziaee
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Tehran, Keshavarz Blvd, Doctor Gharib St., No. 62,
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City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6659 5522
Fax
+98 21 6659 5525
Email
ziaee@tums.ac.ir
Web page address
<http://tums.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Coronary involvement information

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

spss

From where data/document is obtainable

ziaee@tums.ac.ir

What processes are involved for a request to access data/document

Request by email

Comments