Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 group: control group treatment with IVIG2g / kg, aspirin and intervention group treatment with intravenous puls of methyl prednisolone 30 mg /kg in three days and continue with oral prednisolone at a dose of 1 mg / kg for three days . Echocardiographist is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Including criteria :1- age of 6 month to 5 years old 2- complete and incomplete Kawasaki disease definition according to AHA . Excluding 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: IVIG2g / kg, aspirin and 3-day intravenous pulsomethyl 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)
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Email address
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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 Assosiation (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 moreof 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

دکتر وحید ضیایی

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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
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

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Person responsible for scientific inquiries

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Position
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Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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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