

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

comparison effects of two regimens: prednisolone plus cimetidine versus prednisolone plus colchicine in control of frequency and duration of fever episodes In the Periodic fever, Aphthous stomatitis, Pharyngitis and Adenitis in children referred to pediatric medical center

Protocol summary

Study aim

Evaluation and comparison of the effect of prednisolone + cimetidine and prednisolone + colchicine in the treatment of fever and frequency of attacks in PFAPA syndrome

Design

two intervention groups, parallel, triple blind, randomized. The response to treatment is evaluated by comparing the number of fever attacks and the duration of fever periods. Data analysis was performed by SPSS"

Settings and conduct

Children's Medical Center & Vali Asr Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age of onset of symptoms from 1 year to 10 years of age 2. Absence of inflammatory or other rheumatic disease, simultaneously 3. No concomitant disease in which there are contraindications (prednisolone, cimetidine, colchicine). Exclusion criteria: 1. Causing any other rheumatic disease during treatment. 2. Changing the diagnosis of the patient during treatment based on laboratory or clinical symptoms. 3. Lack of proper follow-up and unwillingness to attend the study. 4. Use other treatments that affect the course of the disease, such as specific diets and herbal remedies.

Intervention groups

The study was performed on 80 children with PFAPA syndrome referred to the Pediatric Rheumatology Clinic between October 2019 and June 2020. Patients will be randomly divided into two groups of prednisolone plus cimetidine and prednisolone plus colchicine. The first group will be treated with prednisolone during fever and in addition to prednisolone, cimetidine will be given daily. In the second group, prednisolone is given for fever and will be given daily. The duration of the fever period and the number of fever attacks before and after the

treatment are recorded in a questionnaire. Two visits will take over a period of 3 months

Main outcome variables

Duration of fever "Age" Number of fever attacks "Diagnosis of PFAPA" treatment regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191222045847N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Mahdieh Vahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 8051

Email address

mahvahedi_62@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison effects of two regimens: prednisolone plus cimetidine versus prednisolone plus colchicine in control of frequency and duration of fever episodes In the Periodic fever, Aphthous stomatitis, Pharyngitis and Adenitis in children referred to pediatric medical center

Public title

comparison effects of two regimens: prednisolone plus cimetidine versus prednisolone plus colchicine in control of frequency and duration of fever episodes In the Periodic fever, Aphthous stomatitis, Pharyngitis and Adenitis in children referred to pediatric medical center

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Age of onset of symptoms from 1 year to 10 years of age 2. Absence of inflammatory or other rheumatic disease at the same time 3. there are No concomitant disease that this drugs contraindicated on it (prednisolone, cimetidine, colchicine).

Exclusion criteria:**Age**

From **1 year** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization(given a block size of 4)

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participant, the researcher, the clinical supervisor and the analyzer are not aware of the intended drug intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of school of medicine-Tehran university of medical science

Street address

Deputy of Education, Seventh Floor, Central Organization of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd., Tehran, Iran

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-10-23, 1398/08/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.600

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

PFAPA syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

frequency and duration of fever episodes in PFAPA

Timepoint

Before starting the study and 3 months later

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: PFAPA syndrome patients treated with prednisolone and cimetidine

Category

Treatment - Drugs

2**Description**

Intervention group: PFAPA syndrome patients treated with prednisolone and colchicin

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's Medical Center Hospital

Full name of responsible person

Vahid Ziai

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Boulevard -**City**

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2**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital Complex - Valiasr Hospital

Full name of responsible person

Reza raees karami

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad sahraeeyan

Street addressSixth Floor, Vice Chancellor for Research and
Technology, Qods Street, Keshavarz Boulevard**City**

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Grant name

medical University Tehran

Grant code / Reference number

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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

Mahdieh Vahedi

Position

Pediatric Rheumatology Fellow

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahdieh Vahedi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdieh Vahedi

Position

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Latest degree

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