Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Street address
No.62 , Street Dr. Mohammad , End of Keshavarz Boulevard -
City
tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6147 9000
Email
cmc.tums@gmail.com

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex - Valiasr Hospital
Full name of responsible person
Reza raees karami
Street address
Street Dr. Mohammad , End of Keshavarz Boulevard -
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Email
Imamhospital@tums.ac.ir.com
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 address
Sixth Floor, Vice Chancellor for Research and Technology, Qods Street, Keshavarz Boulevard
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1417653911
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
medical University Tehran
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
Mahdieh Vahedi
Position
Pediatric Rheumatology Fellow
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Mahdieh Vahedi

Position

Pediatric Rheumatology Fellow

Latest degree

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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)

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