Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effect of Cinnarizine and Amitriptyline in Pediatric Migraine Prophylaxis of Children Referring to Children Medical Center Hospital: a Randomized Clinical Trial

Protocol summary

Study aim

Comparison the Effect of Cinnarizine and Amitriptyline in Pediatric Migraine Prophylaxis of Children Referring to Children Medical CenterHospital

Design

This randomized clinical trial, consist of two parallel intervention groups and each one contain 35. The Study is double blinded and the way of randomization is random letter. The phase of the study is: 3.

Settings and conduct

Children aged between 4 and 18 years, who refer to neurology clinic of children medical center hospital for their headaches and are diagnosed with migraine (if she/he be eligible for study) , are referred to one who has not any role in the treatment process. He will randomly divide patients into one of two intervention groups based on letter randomization method. Before starting treatment, patients will initially complete the headache checklist as a baseline information and then will start medication. During this time, headaches details (episode, duration, severity and ...) will be noted in a special checklist prepared for this purpose. Patients will be followed every month and finally after 3 months they will be visited again. Physician will not be aware of patients' groups till the end of the study.

Participants/Inclusion and exclusion criteria

Children with one or more migraine attack experience per month or severe dysfunction in daily or school activities and has not used prophylactic migraine therapy in one previous month and has not focal neurologic deficit and has not known concomitant serious diseases.

Intervention groups

Intervention group 1: Cinnarizine Intervention group 2: Amitriptyline

Main outcome variables

Frequency, severity and duration of headaches episodes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191112045413N1**
Registration date: **2020-01-24, 1398/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-24, 1398/11/04**
Update count: **0**

Registration date

2020-01-24, 1398/11/04

Registrant information

Name

Mehrnaz Olfat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7703 7596

Email address

olfat.mehrnaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the Effect of Cinnarizine and Amitriptyline in Pediatric Migraine Prophylaxis of Children Referring to Children Medical Center Hospital: a Randomized Clinical Trial

Public title
Comparison the Effect of Cinnarizine and Amitriptyline in Pediatric Migraine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having experienced one or more migraine attacks per month or severe dysfunction in daily and school activities
Exclusion criteria:
Use of prophylactic migraine therapy in at least one previous month Focal Neurologic Deficit Known concomitant serious diseases (hepatic, renal, etc)

Age
From **4 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation: Patients will be randomly assigned to two groups of cinnarizine and amitriptyline. The random allocation method of these two groups is block randomization and block size is considered 6 persons and we are using Random allocation software for this process. This sequence will be kept secret with the clerk secretary. None of the participants in the study will be aware of the randomization list and for this purpose we will use color-numbered folders, which will be kept by the clerk secretary who is the only one that know about the allocation groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double blind study. Patients and practitioners and annalist will be unaware of the type of treatment assigned. In order to blind the executive staffs, those applying the treatment will be different from those responsible for examining and evaluating patients. Drug packages will also be labeled according to a specific code. Only the clinic secretary will be informed of the type of drug that patients receive.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
District 6, Keshavarz Boulevard and Ghods St. crossing. Main Office of Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-07-09, 1398/04/18

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.334

Health conditions studied

1

Description of health condition studied
میگرن

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Percent of patients who the severity of their headache episodes decreased to less than 50% of baseline

Timepoint
One month before to 3 months after initiation of treatment

Method of measurement
Visual Analogue Scale and Visual Pain Scale

2

Description
Percent of patients who the frequency of their headache episodes decreased to less than 50% of baseline

Timepoint
One month before to 3 months after initiation of treatment

Method of measurement
By charting all the headache episodes by detail in the special checklist

3

Description
Percent of patients who the duration of their headache episodes decreased to less than 50% of baseline
Timepoint
One month before to 3 months after initiation of treatment
Method of measurement
By charting all the headache episodes by detail in the special checklist

Secondary outcomes

1

Description
Quality of life scoring
Timepoint
One month before to 3 months after initiation of treatment
Method of measurement
PedMIDAS questionnaire

Intervention groups

1

Description
First Intervention group: patients receiving Cinnarizine 25 mg, start with one half of tablet each night and after 10 days, increase to one complete tablet each night, for 3 consecutive months.
Category
Treatment - Drugs

2

Description
Second intervention group: patients receiving Amitriptyline 25 mg, start with one half of tablet each night and after 10 days, increase to one complete tablet each night, for 3 consecutive months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
Mehrnaz Olfat
Street address
No. 62, Mohammad Gharib Street, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6147 2751
Email
cmcpr@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
chancellor for research and technology
Street address
District 6, Keshavarz Boulevard and Ghods St. crossing. Main Office of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Fax
+98 21 8670 5503
Email
vcr@tums.ac.ir
Web page address
http://vcr.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
Mehrnaz Olfat

Position
Pediatric Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
No. 14, Banaei Street, Davoud Armaghani Ave., Damavand Blvd.

City
Tehran

Province
Tehran

Postal code
1643814551

Phone
+98 21 7703 7596

Fax

Email
olfat.mehrnaz@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mehrnaz Olfat

Position
Pediatric Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
No. 14, Banaei Street, Davoud Armaghani Ave., Damavand Blvd.

City
Tehran

Province
Tehran

Postal code
1

Phone
+98 21 7703 7596

Fax

Email
olfat.mehrnaz@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mehrnaz Olfat

Position
Pediatric Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
No. 14, Banaei Street, Davoud Armaghani Ave., Damavand Blvd.

City
Tehran

Province
Tehran

Postal code
1643814551

Phone
+98 21 7703 7596

Fax

Email
olfat.mehrnaz@gmail.com

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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All the information about outcomes will be published

When the data will become available and for how long
6-12 months after publication

To whom data/document is available
Researcher of academic institute

Under which criteria data/document could be used
The data of our study will be accessible by other researchers, for conducting Meta-analysis

From where data/document is obtainable
No decision is made yet

What processes are involved for a request to access data/document
The researchers should explain the aims of their study. The request will be assessed by our team, and if we agree to the request, the requested data will be emailed.

Comments
No further explanation