Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of migrafar (Tanacetum parthenium) on migraine pain in children are treating with amitriptyline

Protocol summary

Study aim
Determining the effect of migrafar on migraine pain in children treated with emitriptyline

Design
The clinical trial has a control group, one blind, randomly divided on 25 patients, randomly divided from A and B cards for randomization. First, it is numbered on paper according to the size of the sample from 1 to 50. Then two groups are randomly created with random elicitation software equal to the sample size and the generated numbers are placed in two study groups. Then, each person entering the study will take a card from the box and depending on the selected card, will be placed in the specified pawn.

Settings and conduct
Outpatients referred to Imam Ali (AS) Shahrekord Clinic, who were visited by the children's neurology department in 1400-1401 and diagnosed with mild to moderate migraine, are studied in order to evaluate the effect of Migrafar capsules.

Participants/Inclusion and exclusion criteria
Definitive diagnosis of migraine headache Mild to moderate headache intensity Not taking any other medicine for headache

Intervention groups
Intervention group: recipient of standard drug Amirtriptyline along with Migrafar capsule Control group: recipient of the standard drug Amirtriptyline along with placebo (which is prepared and provided by Nutekfar pharmaceutical company)

Main outcome variables
The amount of headache-quality of sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220124053815N1**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

Registration date
2023-02-12, 1401/11/23

Registrant information

Name
mehdi sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-06, 1401/09/15

Expected recruitment end date
2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of migrafar (Tanacetum parthenium) on migraine pain in children are treating with amitriptyline

Public title
Investigating the effect of migrafar (Tanacetum

parthenium) on migraine pain in children are treating with amitriptyline

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of primary headache Mild to moderate headache intensity Age range from 6 to 18 years Absence of secondary cause for headache Not taking any other medicine for headache

Exclusion criteria:

Uncertain diagnosis of headache

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be simple. The randomization unit is individual. First, number the size of the sample from 1 to 50 on the paper (the number of papers is equal to 50 and they will be numbered from 1 to 50) and We put these papers in a box. With random allocation software, the members of the sample are divided into two groups, equal to the sample size and randomly in groups. Also, the software randomly generates numbers that will represent the studied group of people. Software address: https://random-allocation-software.software.informer.com/2.0/ Each person who enters the study randomly draws a number from the box and will be studied in one of two groups according to the number he/she takes out of the box. (The numbers inside the box are divided into two groups by the software. And that means, for example, the software has determined that the number 6 should enter the second group, when the subject selects the number 6 from the box, it will enter the second group)

Blinding (investigator's opinion)

Single blinded

Blinding description

Our study will be a one-sided blind study. In this study, the parents and children receiving the medicine will not know about the type of medicine received. The researcher and other people will have complete knowledge about the prescription drugs for each group. Also, the statistical analyst will also He will be aware of the groups and type of medicine received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Kashani street

City

Shahre kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۳۸۳۳۴۳۵

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.SKUMS.MED.REC.1400.009

Health conditions studied

1

Description of health condition studied

Headache, migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

The intensity of the headache will be measured by Visual Scale Questionnaire (VAS)

Timepoint

At the beginning and three months after taking the medicine, we check the result.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Number of headaches

Timepoint

At the beginning of the research and three months after receiving the drug

Method of measurement

Number of daily headaches

2

Description
type of headache
Timepoint
At the beginning of the research and three months after receiving the drug
Method of measurement
To be pulsatile or non-pulsatile

3

Description
Location of headache
Timepoint
At the beginning of the research and three months after receiving the drug
Method of measurement
Unilateral or bilateral

Intervention groups

1

Description
Intervention group: The group receiving the standard drug Amirtriptyline along with Migrafar capsules (prepared and provided by Nutek Far Pharmaceutical Company), which receives one or two capsules daily based on age.
Category
Treatment - Drugs

2

Description
Control group: the group receiving the standard drug Amirtriptyline along with Migrofar placebo capsule (which is prepared and provided by Nutekfar pharmaceutical company), which receives one or two capsules daily based on age.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali (AS) Clinic, Shahrkord
Full name of responsible person
Mehdi Sadeghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahrekord Medical University
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
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehdi Sadeghi
Position
Resident
Latest degree
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.
From where data/document is obtainable
In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address mehdi.sadeghi.68@gmail.com or the contact number 009891103122195.
What processes are involved for a request to access data/document
To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.
Comments