Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Randomized Clinical trial: Citron syrup vs placebo and active controlled in treatment of migraine headache-A one month double blind study.

Protocol summary

Summary

The purpose of this study is to assess the efficacy of Citron juice syrup comparing with placebo and Propranolol in patients with migraine headache in a randomized clinical trial. 115 patients with a clinical diagnosis of migraine headache based on 2nd Edition of The International Headache Classification (ICHD-2) criteria were selected.At last 90 Patients will be randomized into group A (5 cc placebo syrup three times daily after a meal , for 4 weeks), group B (20 mg of Propranolol three times daily after a meal , for 4 weeks) and group C (5cc of Citron juice syrup, for 4 weeks). Patients were evaluated prior to and following 4 weeks of the intervention in terms of the frequency (per month), mean duration (hour, each attack) and mean intensity (visual analogue scale "VAS" 0-10 score) of headache attacks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031012772N1**
Registration date: **2015-04-20, 1394/01/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-20, 1394/01/31

Registrant information

Name

Gholamhossein Yousefi

Name of organization / entity

Shiraz School of Pharmacy, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71124241278

Email address

ghyousefi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Shiraz University of Medical Sciences

Expected recruitment start date

2013-05-06, 1392/02/16

Expected recruitment end date

2013-12-10, 1392/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Clinical trial: Citron syrup vs placebo and active controlled in treatment of migraine headache-A one month double blind study.

Public title

The effect of Citron juice syrup in Treatment of migraine Headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 15-65y; Informed consent persons; 2 headache attacks or more per month; having at least one of the gastrointestinal migraine headache criteria; Not suffering from Diabetes, asthma, COPD, bradycardia, MDD and other neurologic diseases like convulsion; Not pregnancy.Exclusion criteria:Sensitivity to propranolol; use other chemical/herbal drugs within study ; Sensitivity to formulations ingredients;Unpleasant formulation to

patients and desire to exclude; Pregnancy

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Shiraz University of Medical Sciences

Street address
7th floor, Shiraz University of Medical Sciences, Zand street

City
Shiraz

Postal code

Approval date
2013-02-21, 1391/12/03

Ethics committee reference number
CT-91-6451

Health conditions studied

1

Description of health condition studied
Migraine headache

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
mean duration (hour, each attack)

Timepoint
baseline,end of follow up (4 weeks after staring intervention)

Method of measurement
questionnaire

2

Description
frequency of headache (per month)

Timepoint
baseline,4 weeks after treatment

Method of measurement
questionnaire

3

Description
mean intensity of headache attacks

Timepoint
baseline,4 weeks after treatment

Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Placebo Group: Placebo syrup,15 milliliter/Tree times a day for 4 Weeks. Patients Will be Followed at Baseline and 4 Weeks after Starting Intervention.

Category
Placebo

2

Description
Intervention Group:Citron juice syrup,15 mililitr /Three times a day for 4 weeks. Patients will be Followed at Baseline and 4 after Starting Intervention.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Motahhari Clinic, Shiraz University of Medical Sciences

Full name of responsible person
Dr. Mehrnaz Jafarpour

Street address

Zand Avenue, Namazi Square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamhossein Yousefi

Street address

karafarin Street, Roknabad, Quran Gate, Shiraz School of Pharmacy

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz School of Pharmacy

Full name of responsible person

Dr. Mehrnaz Jafarpour

Position

Pharm.D, PhDc Student in Traditional Pharmacy

Other areas of specialty/work

Street address

Karafarin street, Roknabad, Quran Gate, Shiraz School of Pharmacy

City

Shiraz

Postal code

7146864685

Phone

+98 71 3242 4127

Fax

+98 71 3242 4126

Email

mjafarpoor@sums.ac.ir

Web page address

http://pharmacy.sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz School Of Pharmacy

Full name of responsible person

Dr.Gholamhossein Yousefi

Position

Pharm D, PhD, Academic member in the Department of Pharmaceutics, Head of the department of pharmace

Other areas of specialty/work

Street address

Karafarin street, Roknabad, Quran Gate, Shiraz School Of Pharmacy

City

Shiraz

Postal code

7146864685

Phone

+98 71 3242 4128

Fax

+98 71 3242 4156

Email

ghyousefi@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz School of Pharmacy

Full name of responsible person

Dr.Mehrnaz Jafarpour

Position

Pharm.D, PhDc Student in Traditional Pharmacy

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Street address

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Postal code

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Phone

+98 71 3242 4127

Fax

+98 71 3242 4126

Email

mjafarpoor@sums.ac.ir

Web page address

www.sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty