

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of licorice clinical effects on dizziness resulting from propranolol in patients with migraine.

Protocol summary

Summary

The aim of this randomized double-blind placebo-controlled, multicenter in phase 2-3 clinical trial is to assess the effectiveness of licorice extract on prevention of dizziness as a side effect of propranolol in patients with migraine headache. Forty patients with migraine (age 18 to 80 y/o) with systolic blood pressure lower than 120 mmHg, for prophylactic management of migraine with propranolol are enrolled. Patients with hypertension or related remedies, liver, renal, adrenal and diabetic diseases, as well as pregnant participants and those sensitive to licorice are excluded. Based on the neurologist visiting, management protocol involves: 20 mg propranolol two times a day plus Depakine 250 mg a day for two months and subsequently 40 mg propranolol 2 times a day plus Depakine 250 mg a day in third month. Using block randomization, patients are divided into two groups defining case (20 person, licorice two green capsules three times a day) and control (20 person, starch 2 green capsule 3 times a day). Each licorice's capsule contains 350 ± 5 mg licorice extract that is equivalent with 1400 ± 20 mg root of licorice (daily dosage 2100 ± 30 mg licorice extract). Parameters (frequency and severity of dizziness, systolic and diastolic blood pressure and orthostatic hypotension) will be determined at the beginning and 3 months after intervention. The study will also assess the licorice impact on the result of the management of migraine by evaluating frequency and severity of headache with migraine disability assessment test and 0-10 pain scale before and after intervention. Participants who may leave the trial will be substituted with new patients related to this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092219253N1**

Registration date: **2014-10-23, 1393/08/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-23, 1393/08/01

Registrant information

Name

Zahra Bahrami

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3843 0456

Email address

zizi_b68@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of licorice clinical effects on dizziness resulting from propranolol in patients with migraine.

Public title

Effect of licorice on management of migraine.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:40 patients with migraine (age18to80y/o)with systolic blood pressure lower than 120mmhg,for prophylactic management of migraine with propranolol are enrolled. Exclusion criteria: patients with hypertension or related remedies, liver, renal, adrenal,diabetic diseases, as well as pregnant participants and those sensitive to licorice are excluded.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Fars University of Medical Science

Street address

Central building of Shiraz University of Medical Science, Zand street, in front of Palestine street, Shiraz.

City

Shiraz

Postal code

7134814336

Approval date

2014-10-19, 1393/07/27

Ethics committee reference number

CT-P-9347-4147

Health conditions studied

1

Description of health condition studied

migraine headache

ICD-10 code

G43.9

ICD-10 code description

Migraine, unspecified

Primary outcomes

1

Description

frequency of headache

Timepoint

before and 3months after intervention

Method of measurement

counting

2

Description

frequency of dizziness

Timepoint

before and 3months after intervention

Method of measurement

counting

3

Description

prevalence of dizziness

Timepoint

before and 3months after intervention

Method of measurement

report of patient

4

Description

severity of dizziness

Timepoint

before and 3months after intervention

Method of measurement

numeric scale in 5level

5

Description

systolic blood pressure

Timepoint

before and 3months after intervention

Method of measurement

mmhg with mercurial manometer

6

Description

diastolic blood pressure

Timepoint

before and 3months after intervention

Method of measurement

mmhg with mercurial manometer

7

Description

orthostatic hypotension

Timepoint

before and 3months after intervention

Method of measurement

with mercurial manometer in sleeping and standing up position after 2minutes

8

Description

severity of headache

Timepoint

before and 3months after intervention

Method of measurement

pain scale0-10

9

Description

severity of headache

Timepoint

before and 3months after intervention

Method of measurement

migraine disability assesment score test

Secondary outcomes

1

Description

serum potassium

Timepoint

6weeks after intervension

Method of measurement

sampling from patients serum,meq per liter

2

Description

weight

Timepoint

before and3months after intervension

Method of measurement

Kg with Digital weighing- machine

Intervention groups

1

Description

in cases each green capsule contains350±5miligeram extract of licorice ,it is equal with 1400±20miligeram of powder of root of licorice, that will be taken 2capsule 3times a day(at morning,noon,night) with a glass of water.as totally daily dosage will be 2100±30miligeram ectract.

Category

Treatment - Drugs

2

Description

In controls each green capsule contains 350±5miligeram starch,that will be taken 2capsules of starch 3times a day(at morning,noon,night) with a glass of water .as totally daily dosage will be 2100±30miligeram starch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faqihi clinic

Full name of responsible person

zahra bahrami,student of medical science

Street address

Zand street, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Emam Reza clinic

Full name of responsible person

zahra bahrami,student of medical science

Street address

Zand street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Zahra Bahrami

Street address

Central building of Shiraz University of Medical Science, Zand street, Shiraz.

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 Science

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

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7186899411
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Person responsible for general inquiries

Contact

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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