Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of traditionally used remedy from Melissa officinalis L.on benign palpitation in patients reffered to Mostafa khomeini's hospital

Protocol summary

Summary

Aim: study of efficacy of Melissa officinalis L. leaf extract on benign palpitation in patients reffered to Mostafa Khomeini's hospital in 2012-13, randomized double blinded placebo control trial, single center, study population: outpatients with palpitation complaint. Inclusion criteria: age 18-60; palpitation as one of the main complaints. Exclution criteria:serious cardiologic and psychological diseases; pregnancy and lactation; declination of participation; irregular use of prescribed drugs; unpredicted side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012712303N1**
Registration date: **2013-02-24, 1391/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-24, 1391/12/06

Registrant information

Name

Fatemeh Alijaniha

Name of organization / entity

School of traditional medicine, Shahid Beheshti Univerity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

finantial source of school of traditional medicine,Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-11-15, 1391/08/25

Expected recruitment end date

2013-05-19, 1392/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of traditionally used remedy from Melissa officinalis L.on benign palpitation in patients reffered to Mostafa khomeini's hospital

Public title

Effect of Melissa officinalis L. on palpitations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: palpitations (abnormal awareness of heartbeat) as one of the main presenting complaint; history of palpitation for at least three months; age between 18 and 60 years; informed consent. Exclusion criteria: mental retardation; psychosis and other serious psychological diseases confirmed by a psychologist; organic heart diseases confirmed by a cardiologist; serious chronic diseases; pregnancy; lactation; consumption of beta-blockers; consumption of antidepressants and anxiolytics and sedatives 10 days before the start of the study; declination of participation; irregular use of prescribed drugs; unpredicted side effects.

Age

From **18 years** old to **60 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Shahid Behesht University of Medical Sciences
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
Postal code
Approval date
2012-01-07, 1390/10/17
Ethics committee reference number
111

Health conditions studied

1

Description of health condition studied
palpitations
ICD-10 code
R00.2
ICD-10 code description
Awareness of heart beat

Primary outcomes

1

Description
Frequency of palpitations' episodes
Timepoint
Before and after intervention
Method of measurement
asking patients to write it in the form

2

Description
Mean intensity of palpitations' episodes
Timepoint
Before and after intervention
Method of measurement
asking patients to estimate it by VAS and write down in the form

Secondary outcomes

1

Description
Probable mental disorders
Timepoint
Before and after intervention
Method of measurement
validated General Health Questionnaire-28

2

Description
Drug side effects
Timepoint
Before and after intervention
Method of measurement
asking the patients to write their symptoms in the form

Intervention groups

1

Description
Placebo group: Hard gelatin capsule containing 500mg of Melissa leaf dry extract,twise a day,for 14 days
Category
Treatment - Drugs

2

Description
drug groupe: Hard gelatin capsules containing 500 mg of bread powder; twise a day for 14 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mostafa Khomeini Clinic
Full name of responsible person
Fatemeh Alijaniha
Street address
Italia Ave, Felestine Square
City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Traditional Pharmacy,Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mahmoud Mosaddegh
Street address
No.10, Shams Alley, Valiassr Ave.
City
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Traditional Pharmacy,Shahid Beheshti 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
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Person responsible for updating data

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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