

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

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

#### Protocol summary

##### Summary

Aim: study of efficacy of *Melissa officinalis* L. leaf extract on benign palpitation in patients referred 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. Exclusion 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 University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2258 9176

##### Email address

f.aliyaniha@sbm.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

financial 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 referred 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,twice a day,for 14 days

**Category**

Treatment - Drugs

**2****Description**

drug groupe: Hard gelatin capsules containing 500 mg of bread powder; twice 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**

## 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**

Tehran

**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**

School of Pharmacy, Shahid Beheshti University of  
Medical Sciences

**Full name of responsible person**

Fatemeh Alijaniha

**Position**

Pharm.D, Ph.D student (Traditional Pharmacy)

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Shahed University

**Full name of responsible person**

Mohsen Naseri

**Position**

Ph. D, Pharmacology

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## Person responsible for updating data

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Ph.D Student

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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*