Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Survey efficacy of Melissa officinalis on premature ventricular contraction

Protocol summary

Study aim
Determination of the effect of lemon balm on early ventricular heart rate of patients with pulmonary heart disease referred to the clinic of Heshmat Hospital in Rasht

Design
Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct
The samples were selected from among patients with cardiac palpation who were referred to the Hashamat Heart Center. In order to hide the randomization process from sealed envelopes, which were numbered sequentially, the use and envelope of each person was only after confirmation Eligible eligibility criteria for him and signature of the consent form by the individual will be opened.

Participants/Inclusion and exclusion criteria
Entry requirements: No use of sedative drugs, no drug addiction, no history of herbal medicines allergy, palpitations, ages 18-60, PVC less than 15% Non-compliance: Pvc in the field of cardiac ischemia, patients with valvular disorder, heart failure, thyroid dysfunction, anemia, ACS and cardiac approval, psychosis patients and serious psychiatric illnesses certified by a psychiatrist, endocrinology, pregnancy , Taking betablocker medications, treating hypnosis, and treating anti-anxiety and sedative drugs within 10 days before the study, lack of hypothyroidism.

Intervention groups
The intervention group of 36 patients with a diagnosis of pvc less than 15% based on Holter-rhythm will be included in the study and will be visited monthly by the cardiologist and will be treated in the event of symptoms. These patients will use lemon balm, containing 2 grams (25) of Timen's herbs, for 3 months, twice a day. The control group also includes 36 patients with less than 15% of the pvc and monthly asymptomatic, but are not being treated for medication and will be excluded if symptoms develop.

Main outcome variables
premature ventricular contraction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180205038626N4**
Registration date: **2019-07-30, 1398/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-30, 1398/05/08**
Update count: **0**

Registration date
2019-07-30, 1398/05/08

Registrant information
Name
Zahra Ahmadnia
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 13 3361 8177
Email address
zahmadnia@gums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-23, 1398/05/01
Expected recruitment end date
2020-07-22, 1399/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey efficacy of Melissa officinalis on premature ventricular contraction

Public title
Survey efficacy of Melissa officinalis on premature ventricular contraction in Persons with palpitation referring to Dr. Heshmat Rasht Hospital

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Tumors use tranquilizers no addiction no history of allergy to herbal medicines palpitations ages 18-60 PVC less than 15%

Exclusion criteria:
Pvc in the field of ischemic heart disease patients with lupus erythematosus heart failure ACS and cardiologist confirmed psychotic patients and serious psychiatric illnesses certified by a psychiatrist endocrine problems pregnancy Treated with hypnosis and treated with anti-anxiety and sedative drugs within 10 days before the study lack of hypothyroidism thyroid dysfunction

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

Gender
Both

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sequences will be generated using the Random Generator program.Based on the random block method and considering the six blocks, 12 blocks will be generated for 72 patients.After generating the list, each person will be assigned a dedicated code and will be recognized by the code during the study.None of the collaborators participating in the study will be aware of the randomization list, and to use the encryption process to hide the sealed envelopes that are numbered sequentially, the use and envelope of each individual only after confirming the eligibility criteria Study for him and signature of the consent form by the person will be opened.Registration and random allocation sequences are done by the collaborator of the project methodology and assignment of interventions is done by the collaborator of the plan.

Blinding (investigator's opinion)
Single blinded

Blinding description
In order to hide the randomization process from sealed envelopes, which are numbered sequentially, the use and envelope of each individual will be opened only after confirming the eligible eligibility criteria for him and signing the consent form by the individual.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Rasht, Namjoo Ave., Shahid Siadati St., Faced to the 17th Shahrivar Hospital, Old Building, School of Health, University of Technology Research and Technology

City
Rasht

Province
Guilan

Postal code
41446-66949

Approval date
2019-07-21, 1398/04/30

Ethics committee reference number
IR.GUMS.REC.1398.178

Health conditions studied

1

Description of health condition studied
premature ventricular contraction

ICD-10 code
I49.3

ICD-10 code description
Ventricular premature depolarization

Primary outcomes

1

Description
premature ventricular contraction

Timepoint
At the end of the 3-month period, both rituals and echo cancers will be performed and the amount of pvc reduction will be evaluated by the cardiologist.

Method of measurement
Echocardiography, Holler rhythm and ECG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group of 36 patients with a diagnosis of pvc less than 15% based on Holter rhythm will be included in the study and will be visited monthly by a cardiologist and will be excluded from the study in the event of symptoms of shortness of breath, cough, chest pain, pulmonary heart disease. They are under medical treatment. These patients will use lemon balm for 3 months twice a day.
Category
Other

2

Description
Control group: The control group also includes 36 patients with less than 15% of the pvc and monthly asymptomatic, but are not being treated for medication and will be excluded if symptoms develop.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat Rasht Hospital
Full name of responsible person
Arsalan Salari
Street address
Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St.
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4193955588
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salari@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Shadman Nemati
Street address
Namjoo Ave., Shahid Siadati St., Rasht., Technology & Research Vice-chancellor of University
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salari@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
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
Rasht University of Medical Sciences
Full name of responsible person
Arsalan Salari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person

Arsalan Salari

Position
Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available