Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

The study on the effect of Chammomile(Matricaria chamomilla L.)&Lemon balm (Melissa officinalis L.) syrupe on chest pain and quality of life in patient with cardiac syndrome x

Protocol summary

Study aim

primary aims : determination effect of effect of Chamomile & Lemon balm syrup on chest pain and quality of life in patient with cardiac syndrome x secondary aims: 1. design and manufacture of standard chamomile & Lemon balm syrup 2- Comparison of chest pain changes in patients before and after taking the syrup 3- Comparing changes in quality of life in patients before and after taking syrup objective aims: provide a potentially effective treatment for cardiac syndrome x

Design

The study is a single-group clinical trial that for the significance of the study, the required sample size to be maintained by the end of the study was 10 patients.

Settings and conduct

Conducted study: Tehran heart center type of study:single group clinical trial. The target community: patient with drug-resistant cardiac syndrome x Chamomile- Lemon balm syrup was prescribed two times a day, each time as 10 cc, for 90 days

Participants/Inclusion and exclusion criteria

inclusion criteria: Angina- like chest pain positive exercise stress test angiographically normal epicardial coronary arteries drug-resistant cardiac syndrome x,Recurrent chest pain despite conventional treatment at least 6 months, including a combination of two anti-ischemic (beta-blockers, calciتum antagonists) or one anti-ischemic and one alternative(nitrate Statin, ACEI exclusion criteria: sever Valvular heart disease cardiomyopathy coronary spasm LV dysfunction uncontrolled Diabetes mellitus uncontrolled HTN History of myocardial infarction

Intervention groups

single group: chammomile-lemonbalm syroup

Main outcome variables

The overall score of pain in the Seattle angina Questionnaire

General information

Reason for update

Due to the limited access to patient database and non-cooperation in referral of patients after receiving the codeس of ethics and IRCT , after several months to June 2019 and the possibility of easier access to patients' angiography database in Sina Hospital, with the guidance of professors and counselors and council Graduate studies of the faculty, the jury, and Sinai Hospital were added as another center for morbidity, and the angiography database of Sinai Hospital (2016-2017) was used. According to the project's cardiologist, all patients with X-ray heart syndrome should still be treated with diltiazem + atorvastatin for one month, despite previous use of the drug, before entering the study, and if they do not recover after one month.In the period from 2019/5/28 to 2019/9/6 from a 200-person database (2016-2017) of patients with normal angiography and positive ETT , by screening other inclusion and exclusion criteria, only 25 patients had drug resistant angina pain , 17 of the 25 patients had other criteria for entering the study. According to the cardiologist of the project, despite the use of other anti-ischemic in patients, all patients were treated with diltiazem + estrostatin for one month, and if they did not improve later. Within a month, they study were enrolled in the study. seven people were still in pain after a month. then they were enrolled and randomized, after two months follow-up, the study continued with only four people. In the first progress report, due to the lack of sample size required to conduct a study of a 204-person database of patients with normal angiography and positive exercise testing, according to supervisors, counselors and methodologists, the study was conducted as a single group. Let's continue, and the range of common medications prescribed for patients with cardiac syndrome X is a variety of anti-ischemics (calcium blocker, beta-blocker, nitrate) and medications such as

ACE inhibitor, atorvastatin, so for enrolling the patients with drug resistant cardiac syndrome X , instead of prescribing diltiazem and atorvastatin to all patients despite the use of other drugs in the spectrum, Documented drug resistant cardiac syndrome X (persistent chest pain for at least 6 months, despite the use of a maximum dose of a combination of two ischemic compounds (calcium blocker, beta-blocker, nitrate) or a combination of one anti- ischemic and one Alternative drugs such as ACE inhibitor, estrostatin) are approved by the design consultant cardiologist, and the syrup of study is added to conventional drugs in the same way. The study was considered as a pilot in the period of 2019/5/28 to 2019/9/6 ,and based on the analysis of patient response rate, and considering the safety of the drug, it was decided to increase at least dose of of syrup as 5 cc BID to twice as much as 10 cc BID.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180608040014N1**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**
Update count: **1**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Samane Noroozi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-06-04, 1399/03/15

Actual recruitment start date

2019-11-17, 1398/08/26

Actual recruitment end date

2020-01-05, 1398/10/15

Trial completion date

2020-04-08, 1399/01/20

Scientific title

The study on the effect of Chammomile(Matricaria chamomilla L.)&Lemon balm (Melissa officinalis L.) syrupe on chest pain and quality of life in patient with cardiac syndrome x

Public title

The study on the effect of chammomile&lemon balm syrupe in cardiac syndrome x

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Angina- like chest pain positive exercise stress test angiographically normal epicardial coronary arteries no response to treatments in conventional medicine 4. Recurrent chest pain despite conventional treatment at least 6 months, including a combination of two anti-ischemic (beta-blockers, calcium antagonists) or one anti-ischemic and one alternative(nitrate Statin, ACEI)

Exclusion criteria:

sever Valvular heart disease cardiomyopathy coronary spasm LV dysfunction uncontrolled Diabetes mellitus uncontrolled HTN History of myocardial infarction

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **10**
Actual sample size reached: **29**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

According to comments of the methodologist, the sample size required for the significance of the study will be equal to 10 patients, taking into account the index of the Seattle angina Questionnaire, which will be preserved until the end of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

vice-chancellor in research affairs,sixth floor, the Central Organization of Tehran University of Medical Sciences,st.ghods, Keshavarz Blvd,Tehran

City

Tehran

Province

Tehran
Postal code
1417653761
Approval date
2018-11-23, 1397/09/02
Ethics committee reference number
IR.TUMS.VCR.REC.1397.618

Health conditions studied

1

Description of health condition studied
cardiac syndrome x
ICD-10 code
I20.9
ICD-10 code description
Angina pectoris, unspecified

Primary outcomes

1

Description
The overall score of pain in the Seattle Angina Questionnaire
Timepoint
at first and end of study(45 days and 90 days after inclusion in the study)
Method of measurement
the Seattle Angina questionnare

Secondary outcomes

1

Description
Quality of Life Score in SF36 Quality of Life Questionnaire
Timepoint
at enrolling in the study and 45 days and 90 days after enrolling in the study
Method of measurement
SF36 Quality of Life Questionnaire

Intervention groups

1

Description
single group Intervention : chammomile&lemon balm syrupe
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
tehran heart center
Full name of responsible person
دکتر علی واشقانی فراهانی
Street address
Tehran Heart Center-- Jalal Al Ahmad Highway-north kargar Ave-tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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vice-chancellor in research affairs,sixth floor, the Central Organization of Tehran University of Medical Sciences,st.ghods, Keshavarz Blvd,Tehran
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person
Samane noroozi

Position
Ph.D. student

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Other areas of specialty/work
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Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The total potential data can be shared after being unrecognizable in Excel.

When the data will become available and for how long
Up to 5 years after printing results

To whom data/document is available
Researchers at the academic and scientific institutes of people who are in the field of drug production can apply for them.

Under which criteria data/document could be used
1- Performing the same task on heart disease 2- Animal studies 3. drug production

From where data/document is obtainable
Scientific Researcher: Dr. Hossein Rezaezadeh, emai:hosseinrezaeizade@gmail.com tel:09127038842

What processes are involved for a request to access data/document
1-At the request of a magazine after the acceptance of the article for arbitration 2. If a researcher or a drug manufacturer wants to do the same, they can use the data if they refer to this study.

Comments