

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Formulation and evaluation of the efficacy of Myrtus communis syrup in patients with Functional Dyspepsia, A randomized double blind controlled clinical trial

Protocol summary

Study aim

Formulation and Evaluation of the Efficacy of Myrtus communis syrup in patients with Functional Dyspepsia, a randomized double blind controlled clinical trial

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1 on 60 patients

Settings and conduct

This study is conducted in Ajlaliah Clinic of Kermanshah University of Medical Sciences randomly on 46 patients including intervention and control groups. Blinding is performed for patients, clinical caregivers and outcome assessors. Randomization is done using blocks of 4 and 6.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age should be more than 18 years and less than 80 years Body mass index should be between 18 and 35 height per square meter The patient has not been treated with myrtus communis syrup in the past month The disease is suffering from dyspepsia whose type of disease is fully confirmed through complete medical examination, pathology and laboratory information Exit criteria: cancer patients

Intervention groups

Participants are divided into two treatment and control groups: The patients of the treatment group are treated with 5 cc of Myrtus communis syrup per day along with the standard drug (dimethicone) for one month, and the patients of the control group are treated with the standard drug alone. Disease severity and efficacy parameters are evaluated at the beginning (before the intervention) and at the end of the treatment period (after one month).

Main outcome variables

Flatulence, stomach pain, nausea, Esophagitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231005059633N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Negin Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3720 2523

Email address

najafi.ne1998@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and evaluation of the efficacy of Myrtus communis syrup in patients with Functional Dyspepsia, A randomized double bind controlled clinical trial

Public title

Effect of Myrtus communis syrup in treatment of Functional Dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age should be more than 18 years and less than 80 years Body mass index should be between 18 and 35 height per square meter The patient has not been treated with myrtus communis syrup in the past month The disease is suffering from dyspepsia whose type of disease is fully confirmed through complete medical examination, pathology and laboratory information

Exclusion criteria:

cancer patients

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we divide 2 groups that meet the inclusion criteria completely randomly. The randomization process is done using blocks of 4 and 6, and the blocking will be done by the online randomization software www.sealedenvelope.com

Blinding (investigator's opinion)

Double blinded

Blinding description

The double-blind method is used for blinding. The list of intervention groups specified in this process remains with the coordinator. The person responsible for evaluating entry/exit criteria and registering people will not know about this process. None of the patients and the evaluator will know the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

School of pharmacy, Kermanshah university of medical sciences, Daneshgah st. shahid shiroodi Blv. kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.KUMS.REC.1402.161

Health conditions studied

1

Description of health condition studied

Functional dyspepsia

ICD-10 code

K31.8

ICD-10 code description

Other specified diseases of stomach and duodenum

Primary outcomes

1

Description

flatulence

Timepoint

at the beginning of the study (before the intervention) and at the end of the study (after one month)

Method of measurement

Questionnaire

2

Description

stomach pain

Timepoint

at the beginning of the study (before the intervention) and at the end of the study (after one month)

Method of measurement

Questionnaire

3

Description

nausea

Timepoint

at the beginning of the study (before the intervention)

and at the end of the study (after one month)

Method of measurement

Questionnaire

4

Description

Esophagitis

Timepoint

at the beginning of the study (before the intervention)
and at the end of the study (after one month)

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For one month, they are treated with the fruit syrup of the plant in the amount of 5 cc per day along with 2 standard medicines (Dimethicone 40) per day

Category

Treatment - Drugs

2

Description

Control group: they are treated with standard drug (Dimethicone 40) in the amount of 2 tablets per day for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ejlalieh clinic of Kermanshah

Full name of responsible person

Dr. Mehdi Zubairi

Street address

Parking shahrdari, West moallem street, Kermanshah

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najafi.ne1998@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Farzaei

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School of pharmacy, Kermanshah university of medical sciences, Daneshgah st. shahid shiroodi Blv. kermanshah

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Negin Najafi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hossein Farzaei
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

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Name of organization / entity
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Position
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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

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