Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparative study of the effect of eating and drinking modification and sumac capsule with omeprazole on functional dyspepsia symptoms in adults

Protocol summary

Study aim
Comparison of the effect of eating and drinking modification and sumac capsule with omeprazole on reducing the symptoms of functional dyspepsia in adults

Design
This study is a clinical trial with four parallel groups that without blinding It will be performed on 104 patients. Patients will be assigned to one of four groups based on a random allocation with octet blocks.

Settings and conduct
This study is performed in Dr. Mousavi Hospital in Gorgan. In this study, which will be performed as a clinical trial without blindness, 104 patients with a diagnosis of functional dyspepsia are included in the study according to the inclusion criteria. After random allocation, patients will be divided into four groups who will be treated with medication or eating and drinking modification training in the first 4 weeks and will be monitored in the second 4 weeks. Data collection will be done by completing questionnaires by the researcher.

Participants/Inclusion and exclusion criteria
Inclusion criteria: willingness and satisfaction of the patient to participate in the study, functional dyspepsia (based on ROME III criteria), the presence of normal endoscopy without specific pathological findings, no infection with Helicobacter pylori, no antibiotics and PPIs during the last 1 month Exclusion criteria: Underlying diseases including heart failure; Renal and hepatic failure; Cirrhosis; Diabetes, thyroid disorders, smoking, any drugs or alcohol, taking NSAIDs or aspirin, pregnancy or breastfeeding

Intervention groups
Group A patients will receive training on Eating and Drinking Modification and sumac extract capsule, group B patients will receive training on Eating and Drinking Modification, group C patients will receive sumac extract capsule and group D patients will receive omeprazole capsule.

Main outcome variables
Severity of dyspepsia symptoms; Quality of Life; Eating and drinking habits

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200424047192N1**
Registration date: **2021-01-24, 1399/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-24, 1399/11/05**
Update count: **0**

Registration date
2021-01-24, 1399/11/05

Registrant information

Name
Mahdi Saravani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
saravani.m@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of eating and drinking modification and sumac capsule with omeprazole on functional dyspepsia symptoms in adults

Public title

The effect of eating and drinking modification and sumac in the treatment of dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient age range between 18 and 60 years Detection of functional dyspepsia (based on ROME III criteria) Existence of normal endoscopy without specific pathological findings The onset of symptoms is at least 6 months in advance and the presence of symptoms at least 3 days a week in the last three months Absence of Helicobacter pylori infection No history of treatment with antibiotics and PPIs during the last 1 month

Exclusion criteria:

Underlying diseases including heart failure; renal and hepatic failure; dirrhosis; diabetes, thyroid disorders Smoking, drug or alcohol use Consumption NSAIDs or aspirin Pregnancy or breastfeeding

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to one of the following four groups based on a random allocation with octet-blocks previously generated by the Statistics and Methodology Consultant: A- Treatment with eating and drinking modification + sumac capsules B- Treatment with eating and drinking modification C- Treatment with sumac capsules D- Treatment with omeprazole capsules In this study, the number of octet- blocks will be 13. These blocks have 4 letters and each letter has two repetitions. For example, four octet-blocks could be as follows: DCBCDABA, CDBACDAB, ABBCDADC, BACADBCD Accordingly, the first person who enter the study will be assigned to group D, ie treatment with omeprazole capsules, the second person to group C, ie treatment with sumac capsule, and In the same way, assigning participants to study groups up to the last person will be done based on the letters of pre-made blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan Univercity of Medical Sciences

Street address

Phalsaphy complex, Shast kola Road

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.GOUMS.REC.1399.298

Health conditions studied

1

Description of health condition studied

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

Total score of gastrointestinal symptom rating scale

Timepoint

At baseline, 2, 4 and 8 weeks after starting the intervention

Method of measurement

Gastrointestinal Symptom Rating Scale (GSRS) questionnaire

2

Description

Quality of Life

Timepoint

At baseline, 2, 4 and 8 weeks after starting the intervention

Method of measurement

10-item short form of Nepean Dyspepsia Index (NDI-10)

3

Description

Eating and drinking habits

Timepoint

At baseline, 2, 4 and 8 weeks after starting the intervention

Method of measurement

Eating and drinking habits questionnaire

Secondary outcomes

1

Description

Drug side effects

Timepoint

During the intervention and up to one month after the end of the intervention

Method of measurement

Drug side effects questionnaire

Intervention groups

1

Description

First intervention group: observing eating and drinking modification + one capsule of sumac extract after each meal (three times a day). At the first visit (day zero), patients in this group will receive a specific and identical training package including written instruction sheets as well as oral explanations from a PhD student in traditional medicine about following the correct eating and drinking habits and behavior. In addition, patients in this group will receive 42 capsules of sumac extract on the first visit (day zero), of which 3 capsules will be consumed every day as one after each meal. In the second visit, which will be done two weeks after the start of the study, 42 capsules of sumac extract will be delivered to them for consumption in the same way.

Category

Treatment - Drugs

2

Description

Second intervention group: observing eating and drinking modification. At the first visit (day zero), patients in this group will receive a specific and identical training package including written instruction sheets as well as oral explanations from a PhD student in traditional medicine about following the correct eating and drinking habits and behavior.

Category

Lifestyle

3

Description

Third intervention group: one capsule of sumac extract after each meal (three times a day). Patients in this group will receive 42 capsules of sumac extract in the first visit (day zero), of which 3 capsules will be consumed every day as one after each meal. In the second visit, which will be done two weeks after the start of the study, 42 capsules of sumac extract will be delivered to them for consumption in the same way.

Category

Treatment - Drugs

4

Description

Control group: one omeprazole capsule before breakfast (once a day). Patients in this group will receive 14 capsules of 20 mg omeprazole in the first visit (day zero), which will be taken one capsule per day before breakfast. In the second visit, which will be done two weeks after the start of the study, 14 capsules of 20 mg omeprazole will be delivered to them for consumption in the same way.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mousavi Hospital

Full name of responsible person

Mahdi Saravani

Street address

Gorgan university of medical science ,Hirkan blve

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Vice-chancellor of Research and Technology of Gorgan University

Street address

Vice-chancellor of Research and Technology, Gorgan University of Medical Sciences, 5 Km Gorgan, Sari Road

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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
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Mahdi Saravani

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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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