

# 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)

##### Phone

+98 17 3245 1653

##### 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

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Phone**

+98 17 3245 1653

**Email**

dr.msaravani91@gmail.com

**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

**City**

Gorgan

**Province**

Golestan

**Postal code**

4991555876

**Phone**

+98 17 3243 0310

**Email**

Info@goums.ac.ir

**Web page address**

http://goums.ac.ir

**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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**Position**

Student

**Latest degree**

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**Email**

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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