

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of compound honey syrup on Functional Dyspepsia: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim

This study aimed to determine the effect of compound honey syrup in patients with functional dyspepsia

Design

A clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients.

Randomization prepared by Excel

Settings and conduct

Patients aged 18-60 years with Functional Dyspepsia are randomly divided into two groups according to ROME III criteria referred to the gastrointestinal clinic of Imam Hossein Hospital. Patients in the drug group use compound honey syrup. In the placebo group, placebo syrup is used. In the beginning, consent forms and questionnaires on the severity and frequency of symptoms and quality of life are completed. After two weeks, patients are followed up and In the fourth week, patients are re-visited and questionnaires of severity and frequency of symptoms and quality of life are completed.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with Functional Dyspepsia aged between 18 and 60 years. Exclusion: Pregnancy! Breastfeeding! Active urinary tract infection History of seizure! Concomitant use of a chemical or other herbal medicine associated with symptoms of functional indigestion! Any possible severe drug-related side effects! History of a gastrointestinal ulcer or reflux disease! Taking anticoagulants! Irritable bowel syndrome! Surgery in the esophagus and stomach, and intestines! Serious organ diseases such as diabetes and cardiovascular disease! Consumption of any drug! Severe mental retardation The patient's unwillingness to continue the project! Failure to complete the consent form! Warning symptoms (severe weight loss, anemia, blood in the stool, dysphagia)

Intervention groups

Group 1: Recipient of compound honey syrup Group 2: placebo

Main outcome variables

Early satiety; Heaviness; Vomiting; Burning epigastric area; Epigastric pain; bloating; Burp; Nausea; Severity of symptoms; Frequency of symptoms.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046677N6**

Registration date: **2021-02-14, 1399/11/26**

Registration timing: **prospective**

Last update: **2021-02-14, 1399/11/26**

Update count: **0**

Registration date

2021-02-14, 1399/11/26

Registrant information

Name

rasool choopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

rchoopani@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2023-02-18, 1401/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of compound honey syrup on Functional Dyspepsia: a randomized double-blind placebo-controlled clinical trial

Public title
The effect of compound honey syrup on Functional Dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-60 years Patients with functional dyspepsia
Exclusion criteria:
Pregnancy Breastfeeding Active urinary tract infection History of seizure Concomitant use of a chemical or other herbal medicine associated with symptoms of functional indigestion Any possible severe drug-related side effects History of gastrointestinal ulcer or reflux disease Taking anticoagulants Irritable bowel syndrome Surgery in the esophagus and stomach and intestines Serious organ diseases such as diabetes and cardiovascular disease Consumption of any type of drug Severe mental retardation The patient's unwillingness to continue the project Failure to complete the consent form Warning symptoms (severe weight loss, anemia, blood in the stool, dysphagia)

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A table of random numbers will be created by rand Excel software. Before starting, we will determined the direction of selecting random numbers (for example from top to bottom). A series of random numbers will be selected from the table, and even numbers will be assigned to the control group and odd numbers to the intervention group. The codes will be then written on drug labels and kept secretly in an envelope. Containers containing coded drugs and placebo will be provided to the physician and research assistant. Patients start receiving from the smallest number of container to enter the plan. The first patient will be entered into the research will receive the intervention related to smallest code, and the last patient will receive the biggest code.

Randomization unit: individual Randomization tool: Random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
The syrups code will be written to the drugs lable. The Prescribing physician, assistant, and patient will not be aware of syrups' content. (Double-blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2020-09-26, 1399/07/05

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.704

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
Early satiety

Timepoint
At the beginning and end of two weeks and four weeks

Method of measurement
questionnaire

2

Description

Heaviness

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

3

Description

Vomit

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

4

Description

Burning epigastric area

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

5

Description

Epigastric pain

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

6

Description

bloat

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

7

Description

Burp

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

8

Description

Nausea

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

9

Description

Severity of symptoms

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

10

Description

Frequency of symptoms

Timepoint

At the beginning and end of two weeks and four weeks

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Compound honey syrup is produced by NIAK Pharmaceutical Company with the license of the Food and Drug Administration of the Ministry of Health and Medical Education, license number 0425-94-S. This syrup contains ingredients of honey, cinnamon, ginger, saffron, cardamom, kholnjan, mastaki, jozboa and basbaseh, and the instructions for making the medicine according to the manufacturer's instructions are: 1- Honey with 2 times its amount, water poured into the container and mixed. It becomes. 2- The resulting mixture is placed at a temperature of 55 to 60 ° C and under a vacuum of 50 to 70 mm Hg to find the appropriate concentration and its volume reaches two thirds of the total initial volume. 3- From the very beginning of the heat, the semi-finished medicines of ginger, cinnamon, saffron, cardamom, kholnjan, mastaki, jozboa and basbase are poured into cotton bags and hung in a container containing a mixture of water and honey for 24 hours. 4- Then the bag is taken out and the resulting material is smoothed. 5. The resulting solution is packaged in 200 cc bottles. 6- There are 2 grams of cinnamon, 2 grams of cinnamon, 2 grams of cardamom, 1 gram of ginger, 1 gram of sage, 1 gram of saffron and 1 gram of mastic, 1 gram of gooseberry and 1 gram of basil in every 100 cycles of compound honey syrup. 7- Finally, tests of physical characteristics, pH, density, viscosity, dry weight of the extract, microbial and fungal control are performed by NIAK Pharmaceutical Company on the final product.

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup is also prepared by NIAC

Pharmaceutical Company, which is packaged in bottles very similar to compound honey syrup. The placebo will contain water, 0.1% sodium benzoate, 0.1% saccharin and food coloring and the required amount of carboxymethylcellulose.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gastroenterology Clinic of Imam Hossein Hospital

Full name of responsible person

Habib Malekpour

Street address

Shahid Madani Ave - Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

habib.malekpour@gmial.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Esmaeili

Street address

No.8, Valiasr Ave., shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

sesmaeili@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.8, Valiasr Ave., Shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Email

rchoopani@sbmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

No.8, Valiasr Ave., Shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

rchoopani@sbmu.ac.ir

Person responsible for updating data

rchoopani@sbm.ac.ir

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

No.8, Valiasr Ave., Shams Ali

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

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