Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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Province

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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

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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

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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

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

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Person responsible for updating data

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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