

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A study on efficacy of ginger on clinical manifestations in patient with Functional Dyspepsia

Protocol summary

Study aim

Determining the effect of ginger powder on clinical symptoms in patients with functional dyspepsia and comparing it with placebo group

Design

Clinical trial with control group, with parallel groups, triple blind, randomized, phase 2-3 on 70 patients, GraphPad software was used for randomization.

Settings and conduct

After obtaining informed consent for each member of the case and control groups, patients will rank the severity of their symptoms as a pre test. Members of the case group will be given capsules of ginger powder and members of the control group will be given capsules of placebo by the person who distribute capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having Functional dyspepsia, in the age range of 20-60 years, no change in normal diet, do not take NSAIDs, kcl, tetracycline Exclusion criteria: having esophagitis and erosion and peptic ulcer and IBS,

Intervention groups

Case group: 250 mg ginger powder. Control group: 250 mg placebo.

Main outcome variables

Clinical signs of functional dyspepsia include feeling full after eating, feeling full early, feeling epigastric pain, burning sensation in the epigastrium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201103049246N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-25, 1399/10/05**

Update count: **0**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

sina Hassannezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3387 9935

Email address

doctorsina1996@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on efficacy of ginger on clinical manifestations in patient with Functional Dyspepsia

Public title

Ginger in functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have the functional dyspepsia disease Not taking NSAIDs, kcl , tetracycline Be at age range of 20-60 Not

changing normal daily diet

Exclusion criteria:
Have esophagitis, peptic erosion and ulcer, IBS

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the sequences will be determined by using GraphPad software. These sequences will be kept by a person who has no role in other parts of the research. It will be written inside the envelope in a closed and opaque way. Each of these codes falls into one of two groups, A or B. Each patient then will be given their own envelope, which they will give to the person in charge of delivering the medicine. The person in charge of delivering the medicine, depending on the name of the group in which they are located (A or B), will give the medicine of the same part. In each of these parts is either a placebo or capsules containing ginger. In this way, the doctor and the person in charge of drug delivery and patients will not be informed about the type of capsule delivered.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study patients, researcher, Statistics specialist and Physician examining clinical signs will be unaware of the groups allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tabriz university of medical sciences

Street address

floor 5, Afra building, 41th 10 meter, Goldasht station, Zafaranih. Tabriz, Iran

City
Tabriz

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East Azarbaijan

Postal code
5166773186

Approval date
2020-06-08, 1399/03/19

Ethics committee reference number
IR.TBZMED.REC.1399.239

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

Clinical sign's of Functional dyspepsia which include feeling full in the stomach after a meal, feeling full early, feeling epigastric pain and burning sensation in the epigastrium.

Timepoint

At the beginning of the study and 4 weeks after starting capsules which contain Ginger's powder

Method of measurement

Questionnaire prepared from common symptoms of the Functional dyspepsia disease

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group members will be given 250 mg capsule of Ginger's powder (produced by GOLDARU factory of Esfahan with the brand name of Zintoma) 3 capsule daily for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: 3 capsules of 250 mg placebo daily for 4 weeks, patients will complete their disease symptoms as a pre test- posttest.

Category

Treatment - Drugs

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

Gastrointestinal and Liver Disease Research center at Imam Reza hospital of Tabriz

Full name of responsible person

Dr.Mohammad Hossein Somi

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Gastrointestinal and Liver Disease Research center, Floor two, Emergency building, Imam Reza Medical Education Center, Golghast Street, Azadi Avenue, Tabriz

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

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Full name of responsible person

Mohammad Samiei

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Sina Hassannezhad

Position

medical student, intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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

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Full name of responsible person

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Person responsible for updating data

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Position

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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