Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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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, Zaferanieh. Tabriz, Iran

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Province

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
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Sponsors / Funding sources

1

Sponsor
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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
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medical student, intern
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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