

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effects of ginger (zingiber officinale) powder and extract on H.pylori eradication and improvement of clinical signs in patient with H.pylori positive non ulcer dyspepsia

#### Protocol summary

##### Summary

The present study is a randomized double-blind placebo controlled trial that will carry on 120 patients with non ulcer dyspepsia and H. pylori infection who met the inclusion criteria. The first diagnosis of patients done using clinical examination and functional dyspepsia symptom questionnaire. After upper gastrointestinal endoscopy, those volunteers with the diagnosis of H.pylori infection based on Rapid Urease Test, but without any ulcer were enrolled in this study. Duration of study is 30 days and patients after filling an informed consent form and demographic form, will be randomly assigned to one of three groups: intervention 1 (receiving 250 mg of ginger extract as 1 tablet), intervention 2 (receiving 3 grams per day of powdered ginger as 3 tablets) and control (receiving 250 mg per day corn starch as placebo as 1 tablet). The subjects will ask to take the tablets immediately after their meal. The evaluation of eradication of H.pylori will be taken using stool antigen test (HpSA) as an FDA approved technique, one month after the intervention (to avoid false results) and clinical symptoms again by clinical examination and functional dyspepsia symptom questionnaire 1 and 2 months after intervention. Meanwhile, people are asked not to alter their diet during study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211182017N9**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-11-28, 1391/09/08

##### Registrant information

###### Name

Alireza Ostadrahimi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7580

###### Email address

ostadrahimi@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

liver & gastrointestinal diseases research center , Tabriz University of Medical Science

##### Expected recruitment start date

2013-02-03, 1391/11/15

##### Expected recruitment end date

2013-09-06, 1392/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of ginger (zingiber officinale) powder and extract on H.pylori eradication and improvement of clinical signs in patient with H.pylori positive non ulcer dyspepsia

##### Public title

The effect of ginger (zingiber officinale) on H.pylori positive non ulcer dyspepsia

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients aged 65 to 18 years old with dyspeptic symptoms including postprandial fullness, early satiety or upper abdominal pain or burning during the last 3-6 months continuously or intermittently and the endoscopic examination without ulcers, but with H. pylori positive infection based on histological examination or Rapid Urease Test (RUT). Exclusion criteria: age below 18 and above 65 years; peptic ulcer; extreme anorexia; painful swallowing; antibiotics consumption; pregnancy and lactation; having hepatobiliary disease; IBS; jaundice; enlarged lymph nodes in the body; family history of gastric cancer and esophageal history of gastric surgery; frequent vomiting and receiving chemotherapy or NSAIDs intake during the study.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Science

##### Street address

Tabriz, Golgasht street, Attare Neishabouri Avenue,  
Tabriz University of Medical Science

##### City

Tabriz

##### Postal code

#### Approval date

2012-09-24, 1391/07/03

#### Ethics committee reference number

9199

## Health conditions studied

### 1

#### Description of health condition studied

functional Dyspepsia

#### ICD-10 code

k30

#### ICD-10 code description

Dyspepsia

## Primary outcomes

### 1

#### Description

erradication of H.pylori

#### Timepoint

before intervention and one month after the end of intervention

#### Method of measurement

at first by rapid urease test during upper endoscopy and at the end by H.pylori stool antigen test

## Secondary outcomes

### 1

#### Description

dyspepsia clinical symptoms

#### Timepoint

before and after intervention

#### Method of measurement

clinical examination and ROME III dyspepsia symptoms questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: Receiving 3 g/ day dried ginger powder as 3 tablet for 1 month

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Receiving 250 mg/ day ginger extract as 1 tablet for 1 month

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Receiving 250 mg/ day isomalt (as placebo) as 1 tablet for 1 month

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Endoscopy section of Emam Reza hospital

**Full name of responsible person**

Vahideh Ebrahimzadeh Attary

**Street address**

Golgasht Avenue, Attare Neishabouri Street, faculty of Health and Nutrition, Department of Nutrition & Biochemistry

**City**

Tabriz

### 2

#### Recruitment center

**Name of recruitment center**

Golgasht clinic of Tabriz University of Medical Science

**Full name of responsible person**

Vahideh Ebrahimzadeh Attary

**Street address**

Golgasht Avenue, Attare Neishabouri Street, faculty of Health and Nutrition, Department of Nutrition & Biochemistry

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Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

liver & gastrointestinal diseases research center ,  
Tabriz University of Medical Science

**Full name of responsible person**

Dr. Mohammad Hossein Somi

**Street address**

Azadi Avenue, Golgasht Street, Emam Reza hospital

**City**

Tabriz

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

Yes

**Title of funding source**

liver & gastrointestinal diseases research center , Tabriz  
University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

faculty of Health and Nutrition

**Full name of responsible person**

Vahideh Ebrahimzadeh Attary

**Position**

Ph.D Student of Nutrition

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

**Position**

MD, PhD, Associate professor of Nutrition

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## Person responsible for updating data

#### Contact

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Faculty of Health and Nutrition, Department of Nutrition & Biochemistry

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PhD Student of Nutrition

**Other areas of specialty/work**

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**City**

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**Postal code****Phone**

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**Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*