Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of gluten free diet on gastrointestinal symptoms of individuals with idiopathic dyspepsia who referred to the gastroenterology clinics of Imam Khomeini hospital complex and Dr.Shariati hospital in 2017-2018

Protocol summary

Summary

In this study, patients suffering from dyspepsia resistant to treatment and there was no specific cause for them in initial check and celiac disease and allergic to wheat have been ruled out, non-celiac gluten sensitivity (NCGS) are considered. All of the patients underwent 6 weeks of gluten-free diet. Individuals that have no improvement in symptoms, will excluded from our study; but people who have had partial or complete remission, were randomly divided into two groups, as well as being gluten-free diet are for three consecutive weeks. In the first week, one group receive gluten contain muffin and the second group received gluten free muffin (as a placebo), and the recurrence dyspepsia are examined. In the second week, both groups have any muffin. In the third week, the first group receive placebo and the second group give gluten contain muffin and evaluate for recurrence of dyspepsia. This study is a double-blind, conducted in this period (9 weeks), patients are required to follow a gluten-free diet.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031833112N1**
Registration date: **2017-04-22, 1396/02/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-22, 1396/02/02

Registrant information

Name

Mohammad Mahdi Fanaeian

Name of organization / entity

Tehran university of medical science

Country

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Recruitment status

Recruitment complete

Funding source

Investigators, Sahar and Kalleh Food production company

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of gluten free diet on gastrointestinal symptoms of individuals with idiopathic dyspepsia who referred to the gastroenterology clinics of Imam Khomeini hospital complex and Dr.Shariati hospital in 2017-2018

Public title

The effect of gluten free diet on gastrointestinal symptoms of individuals with idiopathic dyspepsia who referred to the gastroenterology clinics of Imam Khomeini hospital complex and Dr.Shariati hospital in 2017-2018

Purpose

Diagnostic

Inclusion/Exclusion criteria
In this study, patients aged 18 to 55 years old suffering from dyspepsia resistant to treatment and there was no specific cause for them in initial check and celiac disease and allergic to wheat have been ruled out, non-celiac gluten sensitivity (NCGS) are considered. All of the patients underwent 6 weeks of gluten-free diet. Individuals that have no improvement in symptoms, will excluded from our study.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2017-02-07, 1395/11/19

Ethics committee reference number
IR.TUMS.IKHC.REC.1395.1675

Health conditions studied

1

Description of health condition studied
Non celiac gluten sensitivity disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Rsolving of intestinal and extraintestinal symptoms

Timepoint
Before the study, at the end of first and third weeks

Method of measurement
Questionnaire of clinical symptoms according to numerical rating scale

Secondary outcomes

1

Description
Serum anti Anti gliadin IgG level, fecal calprotectin

Timepoint
Before the study, at the end of first and third weeks

Method of measurement
Blood tests (ELISA) and stool tests (ELISA)

Intervention groups

1

Description
Gluten free muffins will given to control group for one week.

Category
Treatment - Other

2

Description
Gluten contain muffin (contain about 8gr gluten daily or 160 gr muffin daily) will given to intervention group for one week

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology clinic, Imam Khomeini hospital complex

Full name of responsible person
Tehran Keshavarz Blvd Imam Khomeini Hospital complex gastroenterology clinic

Street address
Dr Mohammad Mahdi Fanaeian

City
Tehran

2

Recruitment center

Name of recruitment center

Gastroenterology clinic, Dr. Shariati hospital

Full name of responsible person

Dr Bijan Shahbazkhani

Street address

Tehran North Kargar Avenue, Dr Shariati hospital Gastroenterology clinic

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Researchers

Full name of responsible person

Mohammad Mahdi Fanaeian

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Researchers

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ms Zebardast

Street address

Training building, Imam Khomeini Hospital Complex, Keshavarz Blvd,

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Fanaeian

Position

Resident of internal medicine

Other areas of specialty/work

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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