Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of curcumin on severity of functional dyspepsia; a three blinded clinical trial

Protocol summary

Study aim
To investigate the efficacy of curcumin on severity of functional dyspepsia.
Design
This study was done as randomized triple-blind placebo-controlled trial with parallel group.
Settings and conduct
The study conducted in between April 2016 and February 2017. Patients were selected from Gastroenterology clinic of Baqiyatallah Hospital (Tehran, Iran).
Participants/Inclusion and exclusion criteria
Eligible patients whom diagnosed with functional dyspepsia according to ROMA III criteria were entered the study. Organic disorders were ruled out by upper gastrointestinal endoscopy. Exclusion criteria was organic disorders according to upper endoscopy, liver dysfunction, renal dysfunction, deterioration of dyspepsia and complications during study period.
Intervention groups
Cases received curcumin capsule contains 500 mg of curcumin (after lunch) daily. For controls placebo capsule exactly the same shape as curcumin capsule was administered daily. Intervention period was 1 month.
Main outcome variables
1. Hong Kong Questionnaire score indicating the severity of symptoms 2. H.pylori antigen in stool

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080901001165N45**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **retrospective**

Last update: **2020-04-03, 1399/01/15**
Update count: **0**

Registration date
2020-04-03, 1399/01/15

Registrant information
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Yunes Panahi
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Baqiyatallah University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-06-09, 1395/03/20
Expected recruitment end date
2017-03-10, 1395/12/20
Actual recruitment start date
2016-06-09, 1395/03/20
Actual recruitment end date
2017-03-10, 1395/12/20
Trial completion date
2017-03-10, 1395/12/20

Scientific title
Effect of curcumin on severity of functional dyspepsia; a three blinded clinical trial

Public title
curcumin in functional dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of functional dyspepsia according to ROMA III criteria Ruled out organic disorders using upper

gastrointestinal endoscopy

Exclusion criteria:

Liver dysfunction Renal dysfunction deterioration of dyspepsia and complications during the intervention

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers was used for randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants did not know whether they consume curcumin or placebo. The appearance of curcumin and placebo were exactly the same. Every patient received an A or B code at the begining of the study which indicated the drug they received during the study. This code was unknown for all of the investigators including who administered drugs, data collectors and also data analyzers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah Medical Sciences University

Street address

Mulla sadra Street

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۹۱۵۳۷۱

Approval date

2017-05-14, 1396/02/24

Ethics committee reference number

29464

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

1.Severity of dyspepsia symptoms

Timepoint

Before intervention, after intervention and 1 month after intervention

Method of measurement

Hong Kong Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: curcumin (C3 complex capsules, Sami Labs, India, containing 500 mg curcuminoids and 5 mg bioperine)

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic of Baqiyatallah Hospital

Full name of responsible person

Yunes Panahi

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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
Bagheiat-allah 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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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable