

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of Curcumin on level of oxidative stress factors and gastric histopathology in patients with chronic gastritis related to helicobacter pylori

Protocol summary

Summary

This study investigated the effects of curcumin on the level of oxidative factors and gastric histopathology in patients with chronic gastritis associated with Helicobacter pylori. Inclusion criteria: Age between 18 to 65 years, confirm of chronic gastritis according to histopathologic assay, presence of abdominal symptoms related to chronic gastritis. Exclusion criteria: recent use of antibiotics in the last 6 months, pregnancy, lactation, recent surgical procedures, alcohol, systemic diseases like coronary artery disease, diabetes, collagen vascular and central nervous system, age <18 years and above 70 years. Patients were divided into two groups of triple therapy regimen and triple therapy regimen+ curcumin. Triple therapy was used in this study as bismuth subcitrate 120 mg / kg four times a day, tetracycline 500 mg / kg four times a day and metronidazole 400 mg / kg three times daily. curcumin was administered by 30 mg two times daily. During the study period was 2 months. All patients were evaluated with endoscopy before and after the intervention. For all patients histological analysis was performed. Gastric mucosal levels of also examined for factors related with oxidative stress, DNA damage and the prostaglandin E2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012826238N1**

Registration date: **2016-03-10, 1394/12/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-10, 1394/12/20

Registrant information

Name

Arezo Judaki

Name of organization / entity

Ilam University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Science, School of Medicine.

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Curcumin on level of oxidative stress factors and gastric histopathology in patients with chronic gastritis related to helicobacter pylori

Public title

Effect of Curcumin on chronic gastritis related to helicobacter pylori

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 65 years; confirm of

chronic gastritis according to histopathologic assay: presence of abdominal symptoms related to chronic gastritis. Exclusion criteria: recent use of antibiotics in the last 6 months; pregnancy; lactation; recent surgical procedures; alcohol; systemic diseases like coronary artery disease; diabetes; collagen vascular and central nervous system; age <18 years and above 70 years.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

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

Ilam University of Medical Sciences

Street address

Ilam University of Medical Sciences

City

Ilam

Postal code

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

ir.medilam.ac.rec.1394.184

Health conditions studied

1

Description of health condition studied

Chronic Gastritis

ICD-10 code

K29.5

ICD-10 code description

Chronic gastritis, unspecified

Primary outcomes

1

Description

Malondialdehyde

Timepoint

Initial and after 8 weeks

Method of measurement

Randox Kit

2

Description

Total Antioxidant Capacity

Timepoint

Initial and after 8 weeks

Method of measurement

Randox Kit

3

Description

Glutathione peroxidase

Timepoint

Initial and after 8 weeks

Method of measurement

Randox Kit

4

Description

prostaglandin E2

Timepoint

Initial and after 8 weeks

Method of measurement

RAI

5

Description

Chronic Gastritis

Timepoint

Initial and after 8 weeks

Method of measurement

Histology

6

Description

Endoscopic Inflammation Score

Timepoint

Initial and after 8 weeks

Method of measurement

Endoscopy

7

Description

DNA Oxidative Damage

Timepoint

Initial and after 8 weeks

Method of measurement

DNA Oxidative Damage Kit

Secondary outcomes

empty

Intervention groups

1

Description

Control group: triple therapy bismuth subcitrate 120 mg / kg four times a day, tetracycline 500 mg / kg four times a day and metronidazole 400 mg / kg three times daily.

Category

Treatment - Drugs

2

Description

triple therapy +Curcumin with 30 mg/twice in day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Gastroenterology Clinic

Full name of responsible person

Arezu Judaki

Street address

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Kourosh Sayhemiri

Street address

Ilam University of Medical Sciences, Boulevard Research, Ban Ganjab, Ilam,Iran.

City

Ilam

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam University of Medical Sciences

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

Ilam University of Medical Science

Full name of responsible person

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Position

Pathologist

Other areas of specialty/work

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Position

Patologist

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