

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Systemic Therapy in patients with dyspepsia with and without Periodontal Therapy for Eradication of Helicobacter Pylori Infection.

Protocol summary

Study aim

Evaluation the efficiency of triple therapy vs combined periodontal and triple therapy in patient with H. pylori positive in the subgingival biofilm.

Design

Two arm parallel group non randomized clinical trial

Settings and conduct

The study was performed in 102 patients with peptic ulcer or dyspepsia, positive for gastric H. pylori infection who refer to gastrointestinal clinic of Alzahra hospital. Individuals who had oral infection were assigned non-randomly to two sets of treatment: a 14-days course of triple therapy (antibiotics, antimicrobials, and proton pump inhibitors) with periodontal therapy (n=32) (G+O+tp) or triple therapy alone groups(n=32) (G+O-t). In all participants the efficacy of H. pylori eradication from the stomach was evaluated 4 weeks after cessation of the triple therapy by H. pylori stool antigen test.

Participants/Inclusion and exclusion criteria

Peptic ulcer or dyspepsia positive for Helicobacter pylori infection based on stool Helicobacter pylori antigen test evaluation

Intervention groups

Test group: course of triple therapy and nonsurgical periodontal therapy control group: course of triple therapy

Main outcome variables

Eradication of gastric Helicobacter Pylori

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110109005570N9**

Registration date: **2021-04-14, 1400/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-14, 1400/01/25**

Update count: **0**

Registration date

2021-04-14, 1400/01/25

Registrant information

Name

Parichehr Behfarnia

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University Of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2021-04-22, 1400/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Systemic Therapy in patients with dyspepsia with and without Periodontal Therapy for Eradication of Helicobacter Pylori Infection.

Public title

The Treatment Effect of Nonsurgical Periodontal Therapy for Eradication of Helicobacter Pylori Infection Following Systemic Therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Peptic ulcer or dyspepsia positive for helicobacter pylori infection based on stool helicobacter pylori antigen test evaluation or serology

Exclusion criteria:

Suffering from MALT Zolinger Elison syndrome GI tract cancer Liver and kidney disease Tacking antibiotics or probiotic in past 4 weeks or any contraindication for tacking medicinal diet Immunologic disease Pregnancy History of upper GI tract surgery History of eradication of Helicobacter pylori infection History of tacking PPI Do not take medication regularly(20% or more) Serious side effect as a result of tacking medication Request a patient to leave the study Failure for oral hygiene.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committe of Isfahan University Of Medical Sciences

Street address

Hezar Jarib St

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Esfahan

Province

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Postal code

8174673461

Approval date

2016-06-14, 1395/03/25

Ethics committee reference number

IR.MUI.REC.1396.3.174

Health conditions studied

1

Description of health condition studied

Peptic ulcer or dyspepsia

ICD-10 code

K27

ICD-10 code description

Acute peptic ulcer

Primary outcomes

1

Description

The presence of H. pylori in GI tract and its eradication

Timepoint

Base line(before treatment), 1 months after treatment

Method of measurement

Stool H. pylori antigen test

2

Description

Presence of H. pylori in dental plaque

Timepoint

Base line(before treatment)

Method of measurement

Rapid Urease Test

Secondary outcomes

1

Description

Probing depth

Timepoint

Base line(before treatment),1 months after treatment

Method of measurement

Probing by Williams prob, from gingival margin to depth of pocket

2

Description

Plaque index

Timepoint

Base line(before treatment) and 1 months after treatment

Method of measurement

Plaque index of silness and loe

Intervention groups

1

Description

Triple therapy (G +O +tp)include pantoprazol 40mg q2d,Bismuth sub-citrate 240mg q2d,amoxycillin 1gr q2d, Clarithromycin 500 for 14 days.. non surgical treatment consist of oral hygiene instruction and scaling and root planing.

Category

Treatment - Drugs

2

Description

Nonsurgical periodontal therapy : scaling and root planning

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinics of Isfahan Medical University

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Isfahan University Of Medical Sciences

Full name of responsible person

Dr shaghayegh haghju

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Grant name

تحقیقاتی

Grant code / Reference number

396174

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

Yes

Title of funding source

Vice chancellor For Research Of Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shirin Rostami

Position

Periodontist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable