Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Isfahan University of Medical Sciences

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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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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
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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
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Shirin Rostami
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Periodontist
Latest degree
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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