

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of effects of treatment of periodontal disease on recurrence of dyspeptic symptoms emanating from Helicobacter Pylori in patients who underwent systemic Antibiotic therapy

Protocol summary

Summary

The aim of the study is evaluation of effects of periodontal treatment on recurrence of dyspeptic symptoms emanating from Helicobacter Pylori. Target sample consists of 60 patients referred to the department of Gastroenterology of Shahid Sadoughi hospital for dyspeptic symptoms and specified chronic periodontitis. Presence of Helicobacter Pylori in gastrointestinal tract is confirmed by means of Stool Exam and in sub gingival plaque by means of Rapid Urease Test. Any patient who takes local or systemic antimicrobial agents, Proton Pump Inhibitors, H2-blockers and Bismuth from one month before the study, reports a history of upper gastrointestinal tract bleeding or abdominal cancer, has a systemic condition such as Diabetes Mellitus, smokes, underwent periodontal treatment within the past 6 months, is pregnant or is older than 60 years is excluded from the study. We randomly allocate a number from the set of numbers 1 to 60 to each patient that is done by random selection of a member of the set in a manner that all the members have equal probability of selection. This procedure is done by the aid of a computer program. We divide the set to two partitions. The first partition is the set of numbers 1 to 30 and the second partition contains the set of numbers 31 to 60. Patients of the first partition are considered as case and patients of the second partition are considered as control group. Patients in both groups undergo systemic antibiotic therapy and eradication of the bacteria in gastrointestinal tract is confirmed by Urea Breath Test. Periodontal pocket reduction treatment is done for one of the groups and the other remains untreated. Patients are asked for recurrence of dyspeptic symptoms 2, 4 and 6 months after completion of antibiotic therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042913167N1**

Registration date: **2013-08-22, 1392/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-22, 1392/05/31

Registrant information

Name

Maryam Nourelahi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1725 5873

Email address

m.noorelahi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Shahid Sadooghi Yazd University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of treatment of periodontal disease on recurrence of dyspeptic symptoms emanating from Helicobacter Pylori in patients who underwent systemic Antibiotic therapy

Public title

Treatment effect of gum disease on recurrence of maldigestion in cases with antibiotic therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Patients older than 20 years who are referred to the department of Gastroenterology of Shahid Sadoughi hospital for dyspeptic symptoms, periodontal disease is diagnosed in them and the presence of Helicobacter Pylori is confirmed in gastrointestinal tract and sub gingival plaque sample. Exclusion criteria includes: 1- Taking local or systemic antimicrobial agents, Proton Pump Inhibitors, H2-blockers and Bismuth from one month before the study. 2- History of upper gastrointestinal tract bleeding or abdominal cancer. 3- Presence of systemic conditions such as Diabetes Mellitus. 4- Smoking. 5- Undergoing periodontal treatment in the past 6 months. 6- Pregnancy. 7- Being older than 60 years.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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**

Ethics Committee, Shahid Sadoughi Yazd University of

Medical Sciences

Street address

Central organization of Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Square

City

Yazd

Postal code

8916978477

Approval date

2013-03-04, 1391/12/14

Ethics committee reference number

17/1/183087/پ

Health conditions studied**1****Description of health condition studied**

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Indigestion

2**Description of health condition studied**

periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes**1****Description**

Recurrence of Dyspepsia emanating from Helicobacter Pylori

Timepoint

2, 4 and 6 months after completion of antibiotic therapy

Method of measurement

Asking the patients on the phone

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Periodontal pocket reduction therapy by first non surgical and then surgical therapy (different types of flap surgery) after about a month+ 500mg Amoxicillin and 250mg Metronidazole three times a day for two weeks

Category

Treatment - Surgery

2

Description

Control group: 500mg Amoxicillin and 250mg Metronidazole three times a day for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Gastroenterology, Shahid Sadoughi hospital

Full name of responsible person

Hasan Salman Roghani

Street address

Department of Gastroenterology, Shahid Sadoughi hospital, Shahid Dashti Blvd.

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Shahid Sadoughi Yazd University of Medical Sciences

Full name of responsible person

Fateme Ezodini

Street address

Central Organization of Shahid Sadoughi Yazd university of Medical Sciences and Health Services- Shahid Bahonar Sq.

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research and technology, Shahid Sadoughi Yazd 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi Yazd university of Medical Sciences

Full name of responsible person

Ahmad Haerian Ardakani

Position

Associate Professor

Other areas of specialty/work

Street address

Periodontics Department, School of Dentistry, Dahe fahr Blvd.

City

Yazd

Postal code

Phone

+98 35 1621 4257

Fax

Email

ahmad.haerian@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi Yazd university of Medical Sciences

Full name of responsible person

Ahmad Haerian Ardakani

Position

Associate Professor

Other areas of specialty/work

Street address

Periodontics Department, School of Dentistry, Dahe fahr Blvd.

City

Yazd

Postal code

8916978477

Phone

+98 35 1621 4257

Fax

Email

ahmad.haerian@gmail.com

Web page address

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