Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Bahounar 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 fajr 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 fajr 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