Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Helicobacter pylori eradication on patients suffering rosacea: a clinical trial study

Protocol summary

Summary

Objectives: The aim of this study is to determinate the effects of H. pylori eradication on patients suffering Rosacea who, at the same time, have clinical and serological evidence of H. pylori infection. Design, Setting and Conduct: This non-randomized clinical trial study will be taken place in Gastrointestinal diseases department of Tabriz Emam Reza educational-clinical center during 6 months (August 2015-March 2016) Participants including major eligibility criteria: 150 patients who are 20-65 years old and suffering rosacea and h.pylori infection will be randomly selected and included in study , while excluding pregnant patients or those suffering an co-existing dermatologic problem. Intervention: All patients will undergo a precise assessment of rosacea condition using Duluth Rosacea Scoring Scale by a dermatologist. These patients will undergo a standard two-week course of treatment for H. pylori infection which includes metronidazole 500 mg orally twice a day, clarithromycin 500 mg orally twice a day, and pantoprazole 40 mg orally daily. All patients after undergoing eradication protocol will be assessed once more 60 days later by the dermatologist to examine Rosacea stage. Main outcome measures: outcome measurements will be made at the beginning (day 0) and the end of the trial (day 60) by a dermatologist using the Duluth Rosacea Scoring Scale. At last before and after therapy Duluth Rosacea Scores will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051418946N3**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name
Reza Piri
Name of organization / entity
Emam Reza educational-medical center, Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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+98 41 3334 5372
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Helicobacter pylori eradication on patients suffering rosacea: a clinical trial study

Public title

Effect of Helicobacter pylori eradication on patients suffering rosacea: a clinical trial study

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: confirmed H.pylori infection; Suffering Rosacea. Exclusion criteria:patients older than 65 and younger than 20; Existanse of any other dermatologic problem; patients refusal to continue study in any stage of study; allergy to clarithromycin, omeprazole; pregnant or breast-feeding; antibiotic therapy within the past 2 months; topical treatment of rosacea in past 3 weeks
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz university of medical sciences, Golgasht street, Azadi avenue
City
Tabriz
Postal code
Approval date
2014-02-24, 1392/12/05
Ethics committee reference number
5/4/854

Health conditions studied

1

Description of health condition studied
Rosacea
ICD-10 code
L71
ICD-10 code description
Rosacea

Primary outcomes

1

Description
Duluth Rosacea Scoring Scale
Timepoint
Before eradication- 60 days after study beginning
Method of measurement
Assessing by dermatologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:These patients will undergo a standard two-week course of treatment for H. pylori infection which includes metronidazole 500 mg orally twice a day, clarithromycin 500 mg orally twice a day, and pantoprazole 40 mg orally daily. All patients after undergoing eradication protocol will be assessed once more 60 days later by the dermatologist to examine Rosacea stage.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza medical-educational centre, Tarbiz University of medical sciences
Full name of responsible person
Dr.Parviz Saleh
Street address
Emam Reza educational-medical centre, Golgasht street, Azadi Avenue
City
Tarbiz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Central campus of Tabriz University of Medical Sciences, Golgasht street, Azadi avenue

City

Tabriz

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, Tabriz 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

Emam Reza educational-medical center

Full name of responsible person

Dr.Parviz Saleh

Position

Associate professor of tropical and infectious diseases

Other areas of specialty/work

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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