

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the treatment of rosacea patients after eradication of *Helicobacter pylori* infection and treatment with topical gel of metronidazole 75% in comparison with control.

Protocol summary

Study aim

Determining the improvement of rosacea patients after *Helicobacter pylori* infection eradication and treatment with topical gel of metronidazole 75% compared to control.

Design

This randomized clinical trial study will be performed in 2021 at Skin Diseases and Leishmaniasis Research Centre in Isfahan city. First, ELISA test (to determine the level of IgG and IgM against *Helicobacter pylori*) and EIA test (to determine *Helicobacter pylori* antigen in the stool) will be performed for 62 patients with rosacea.

Settings and conduct

This randomized clinical trial study will be performed in 2021 at Skin Diseases and Leishmaniasis Research Centre in Isfahan city. After confirmation of *Helicobacter pylori* infection, patients are randomly divided into two groups: As, in the intervention group, in addition to the standard treatment with topical gels, 3 antibiotics are applied for two weeks in order to eradicate the infection. In comparison group only treatment with topical gels will be prescribed. After completion of treatment in both intervention and comparison groups, ELISA (enzyme-linked immunosorbent assay) and EIA (enzyme-linked immunosorbent assay) tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Ages 17-65 2) Subjects with Rosacea
Exclusion criteria: 1) Gastrointestinal symptoms 2) Age less than 17 and more than 65 3) Pregnancy or breastfeeding 4) Antibiotics (Bismuth subsalicylate) 6) Use of proton pump inhibitors (Nexium and Prilosec) during the one month before the start of the study.

Intervention groups

The intervention group, in addition to standard treatment with topical gels, receives triple antibiotics. The comparison group uses only therapy with topical gels.

Main outcome variables

H. pylori antigen, IgM against H. pylori, IgG against H. pylori Lesion area.

General information

Reason for update

Acronym

HP

IRCT registration information

IRCT registration number: **IRCT20201116049400N1**

Registration date: **2021-07-30, 1400/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-30, 1400/05/08**

Update count: **0**

Registration date

2021-07-30, 1400/05/08

Registrant information

Name

seyed hossein hejazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the treatment of rosacea patients after eradication of *Helicobacter pylori* infection and treatment with topical gel of metronidazole 75% in comparison with control.

Public title

The effect of eradication of *Helicobacter pylori* infection in the treatment of rosacea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 17-56 Subjects with rosacea

Exclusion criteria:

Gastrointestinal symptoms (bloating, nausea, high intestinal upset, premature satiety, heartburn, ...) Age less than 17 and more than 65 years Antibiotics (Bismuth subsalicylate) for the treatment of *Helicobacter pylori* eradication Use of proton pump inhibitors (Nexium and Prilosec) during the month before the start of the study Pregnancy or Breastfeeding

AgeFrom **17 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

After confirmation of *Helicobacter pylori* infection in patients with rosacea, they are divided into two groups based on restricted simple randomization of block randomization.: group 1 (intervention) and group 2 (comparison). Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to ensure that the number of samples assigned to each of the study groups is equal in cases where intermediate analyzes are required during the sampling process. The size of all blocks is equal and in this two-group experiment, we will have 20 blocks (including 3 participants in the intervention group and 3 participants in the control group). For randomization tools, random allocation software is used. These random sequence generation software, in addition to simple randomization, are able to generate random sequences by blocking method.

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 Of Isfahan University Of Medical Sciences

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Hezar Jarib Street

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Isfahan

Postal code

81746-73461

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.MUI.MED.REC.1399.628

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

Rosacea

ICD-10 code

L71

ICD-10 code description

Rosacea

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

Determination of Immunoglobulin G (IgG) and Immunoglobulin M (IgM) levels of *Helicobacter pylori* and qualitative determination of *Helicobacter pylori* antigens

Timepoint

Measurement of IgG and IgM levels of *Helicobacter pylori*, evaluation of the presence of *Helicobacter pylori* antigen in the feces of patients and lesion size (before the intervention) and 2 months after the start of topical antibiotics and gels.

Method of measurement

ELISA (Enzyme-Linked Immunosorbent Assay), EIA (Enzyme Immunoassay)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the standard treatment with Metro Nidazole 75% topical gel (Metromax produced by Tehran Shimi Company) (twice a day), in order to eradicate the infection for two weeks, triple antibiotic treatment with clarithromycin 500 mg (twice a day) (Pharmacy Laboratory) Day of medicine), amoxicillin 1 g (twice a day) (Kosar Pharmaceutical Company) and omeprazole 20 mg (twice a day) (Sanamad Pharmaceutical Company) are applied.

Category

Treatment - Drugs

2

Description

Control group: In the case of the comparison (control) group, treatment with topical metronidazole 75% gel (twice daily) (Metromax produced by Tehran Shimi Company) will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Leishmaniasis And Skin Diseases Research Center

Full name of responsible person

Dr. Zabih Allah Shahmoradi

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Jomhoori Square , Khoram Street, Sedighe And Tahereh Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, 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

Dr. Seyed Hossein Hejazi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Parasitology

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available