Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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 comparisongroup 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. pylor, 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
Age
From **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
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfehan
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

Street address
Jomhoori Square , Khoram Street, Sedighe And Tahereh Clinic

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Sponsors / Funding sources

1

Sponsor

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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
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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