Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Review the effectiveness of omeprazole and doxycycline with erythromycin topical solution 4% in the treatment of acne vulgaris lesions

Protocol summary

Summary

Objective: To assess the effectiveness of omeprazole and erythromycin topical solution with 4% doxycycline in the treatment of acne vulgaris lesions. Design: This study is a randomized clinical trial (Randomized Clinical Trial) and studied, patients with moderate acne lesion will.Setting & control: Patients were randomly assigned to two groups, one group treated with omeprazole plus 4% solution of topical erythromycin and doxycycline second group treated with topical 4% erythromycin solution, were treated for three months Before treatment, all patients will be tested for H. pylori.Participation including:The diagnosis of acne average = Score EGGS 3; lack of sensitivity to macrolides and proton pump inhibitors; lack of active liver disease or kidney; Not taking warfarin; Phenytoin, diazepam; Older than 12 years; 17 to 40 inflammatory lesions (papules, nodules, pustules) and 20 to 100 comedone closed or open Bashnd.Intervention:omeprazole 20 mg tablet daily with 4% Erytrvmasyn 4% solution Pak Daru 2-doxycycline capsules 100 mg daily with 4% Erythromycin solution Pak Daru.Main outcome measures: Demographic characteristics of patients, skin and non-skin side effects, location withdrawals, the number of inflammatory lesions (papules, pustules and comedone), inflammatory lesions responded to treatment and the level of satisfaction (questionnaire).Patients at weeks 2, 4, 6, 8, 10 and 12 be evaluated.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016012625916N3**
Registration date: **2016-03-14, 1394/12/24**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-03-14, 1394/12/24

Registrant information

Name

Fariba Jaffary

Name of organization / entity

Skin disease & Leishmaniasis Research Center-Seddigheh Tahereh Center

Country

Iran (Islamic Republic of)

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+98 33373736

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Review the effectiveness of omeprazole and doxycycline with erythromycin topical solution 4% in the treatment of acne vulgaris lesions

Public title

Effect of omeprazole and doxycycline with erythromycin

topical solution 4% for the treatment of acne lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included a diagnosis of acne = Score EGGS 3; insensitivity to macrolides and proton pump inhibitors: lack of active liver or kidney disease; avoiding the use of warfarin; phenytoin; diazepam:Older than 12 years;17 to 40 inflammatory lesions (papules, nodules, pustules);20 to 100; closed or open comedones .Exclusion criteria:patients with criteria for pregnancy and lactation; allergic reactions to medications; exacerbation;Astringent and topical abrasive consumption one week before the start of treatment;topical treatment of acne products; including soaps; antimicrobial consumption and comedogenic products for 2 weeks before treatment;The use of topical retinoids; retinol and systemic acne treatments one month before treatment; the use of systemic retinoids 6 months befor of treatment;oligomenorrhea;Hirsutism;taking OCP; systemic antibiotics for at least 1 month before treatment;fulminant;body acne alone.

Age

From **12 years** old to **44 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street thousand acres

City

Isfahan

Postal code

Approval date

2010-03-14, 1388/12/23

Ethics committee reference number

288280

Health conditions studied

1

Description of health condition studied

Acne volgaris

ICD-10 code

l00- l08

ICD-10 code description

infectios of the skin and subcutaneos tissue

Primary outcomes

1

Description

The clinical remission and response to treatment of inflammatory lesions.

Timepoint

Patients at weeks 2, 4, 6, 8, 10 and 12 will be evaluated

Method of measurement

the improvement of clinical acne, severity and response to treatment of inflammatory lesions (80% and above = good - between 50 and 79% = middle = 20% and down 49% = less = no response) to be discussed.

Secondary outcomes

1

Description

Side effects

Timepoint

Weeks 2, 4, 6, 8, 10 and 12

Method of measurement

History and clinical observation

Intervention groups

1

Description

Intervention group 1: 34 patients will be treated with tablets omeprazole 20 mg (one a day) with a solution of erythromycin topical 4%Pak Daru (twice daily)

Category

Treatment - Drugs

2

Description

Control group:34 atients will be treated with Doxycycline 100 mg capsule daily with 4% Erythromycine solution Pak twice daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Skin Disease & Leishmaniasis Research Center

Full name of responsible person
Dr.Fariba Jaffary

Street address
Street Khorram - Tahereh. Seddigheh. Research Center

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Akram Mazaheri

Street address
Hezar Jrib Street, Isfahan University of Medical Sciences and Health Services, Building No. 4 of Vice, Vice chancellor for research

City
Isfahan

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, Isfahan 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
Skin disease & Leishmaniasis Research Center

Full name of responsible person
Hanieh Sharifian

Position
MS-Researcher

Other areas of specialty/work

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PHD Pharmacology,Associate Professor

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Web page address

Person responsible for updating data

Contact

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