

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of dapsone 5% Topical gel with metronidazole 0.75% efficacy in combination with oral doxycycline In papulopustular rosacea

Protocol summary

Summary

Rosacea is an inflammatory disease of the pilosebaceous units. Various systemic and topical options are available for its treatment. Topical dapsone is an antibacterial and anti-inflammatory agent for rosacea treatment. The goal of this study is comparison between topical dapsone 5% gel with metronidazole 0.75% gel efficacy in combination with oral doxycycline in treatment of facial papulopustular rosacea. This study is a double blind (both patients and practitioners were blind to the trial), randomized, clinical trial. This study contains two randomized group using table of randomization and 28 patients present in each group (in total 56 patients). Fifty six adult (18-55 years) patients with at least 5 lesions of papulopustular rosacea were enrolled. Inclusion criteria were age between 18 and 55, patients with papulopustular facial rosacea and exclusion criteria were pregnancy or lactation, any history of G6PD deficiency or history of hypersensitivity to dapsone or metronidazole. The severity of disorder was determined by the patient according to visual analogue score (VAS) Investigator's global assessment (IGA) scores and number of inflammatory lesions were recorded. 5% dapsone gel was administered for group D and 0.75% metronidazole gel was administered for group M. Systemic doxycycline was administered for all patients. follow up assessments were done at 4, 8 and 12 weeks. The primary end points were change in IGA scores and number of inflammatory lesions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010516079N1**

Registration date: **2014-04-26, 1393/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-26, 1393/02/06

Registrant information

Name

Parastoo Khosravani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1669 3682

Email address

p_khosravani@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-04-10, 1392/01/21

Expected recruitment end date

2013-11-01, 1392/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dapsone 5% Topical gel with metronidazole 0.75% efficacy in combination with oral doxycycline In papulopustular rosacea

Public title

Dapsone gel in the treatment of papulopustular rosacea

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: age between 18 and 55, patients with papulopustular facial rosacea, negative history of using topical steroid or retinoic acid during last month, negative history of using oral anti-inflammatory agents and oral retinoic acids during last month and last 180 days respectively Exclusion criteria: Pregnancy or lactation, any history of G6PD deficiency, any history of hypersensitivity to dapsone or metronidazole, any history of oral cotrimoxazole treatment

Age
 From **18 years** old to **55 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **56**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Double blinding in this study was done in a manner that both patients and researchers were not aware that which kind of exposure was done. In fact Metronidazole and dapsone topical preparations had the same appearance and only by a code placed in an envelope it could be determined whether the agent is actual drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Aven, Isfahan

City

Isfahan

Postal code

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

39208

Health conditions studied

1

Description of health condition studied

Papulopustular Rosacea

ICD-10 code

L71.8

ICD-10 code description

Other rosacea

Primary outcomes

1

Description

Rosacea papulopustular lesions

Timepoint

Baseline, week 4, week 8, week 12

Method of measurement

Number of inflammatory lesions, Visual analogue score (VAS.) and Investigator's global assessment scores (IGA.)

Secondary outcomes

1

Description

Side effects of drug

Timepoint

Every 4 weeks

Method of measurement

clinical evaluation-laboratory test

Intervention groups

1

Description

Topical 5% dapsone gel were administered for group D and applied on the face twice daily for 12 weeks with systemic doxycycline capsule (Sobhan Darou Co.), 100 mg/day. Mode of use and application in the study: apply twice a day, every day, for 12 weeks. The cases are advised to wash the entire affected area with a mild cleanser and pat dry with a clean towel then apply a thin layer of the gel onto the entire affected area (a pea-sized amount will usually be enough), then gently and completely rub the gel right into their skin. In order to supply the dapsone gel, dapsone powder was dissolved in ethanol and then prepared in gel vehicle up to 5% concentration. Powder of dapsone, odorless crystalline powder, is applied in an aqueous gel base for topical dermatologic use. Base or vehicle of the gel is composed of: Diethylene Glycol Monoethyl Ether; Methylparaben; Sodium Hydroxide; and purified water. Treatment and total follow up period was 12 weeks.

Category

Treatment - Drugs

2

Description

Topical 0.75% metronidazole gel were administered for group M and applied on the face twice daily for 12 weeks with Systemic doxycycline capsule (Sobhan Darou Co.), 100 mg/day. Mode of Use and application in the study: apply twice a day, every day, for 12 weeks. The cases are advised to wash the entire affected area with a mild cleanser and pat dry with a clean towel then Apply a thin layer of the gel onto the entire affected area (a pea-sized amount will usually be enough), then gently and completely rub the gel right into their skin. Topical Metronidazole gel was prepared similar in shape, odor, size and color to dapson gel, and applied in an aqueous gel base for topical dermatologic use. Base or vehicle of the gel is composed of: Diethylene Glycol Monoethyl Ether; Methylparaben; Sodium Hydroxide; and purified water. treatment and total follow up period was 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital, dermatology clinic

Full name of responsible person

Dr. Parastoo Khosravani

Street address

Dermatology group, Al-zahra hospital, Soffeh Blvd, Isfahan

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

Dr. Ebrahim Esfandiari, Vice chancellor for research, Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Aven, Isfahan

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Parastoo Khosravani

Position

Resident of dermatology

Other areas of specialty/work

Street address

Dermatology group, Al-zahra hospital, Soffeh Blvd, Isfahan

City

Isfahan

Postal code

Phone

+98 31 1625 5555

Fax

Email

p_khosravani@resident.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Gita Faghihi

Position

Professor Of Dermatology

Other areas of specialty/work

Street address

Dermatology group, Al-zahra hospital, Soffeh Blvd, Isfahan

City

Isfahan

Postal code

Phone

+98 31 1625 5555

Fax

Email

G_faghihi@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Parastoo Khosravani

Position

Resident of dermatology

Other areas of specialty/work**Street address**

Dermatology group, Al-zahra hospital, Soffeh Blvd,
Isfahan

City

Isfahan

Postal code**Phone**

+98 31 1625 5555

Fax**Email**

p_khosravani@resident.mui.ac.ir

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