Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of 5% dapsone gel plus oral isotretinoin with oral isotretinoin alone in young patients with moderate to severe facial acne

Protocol summary

Summary

Acne vulgaris 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 acne treatment .This study aimed to evaluate the efficacy of combination of 5% dapsone gel and systemic Isotretinoin in acne vulgaris. A Double-blind(both patients and practitioners were blind to the trial), randomized, placebo-controlled, clinical trial was done on 58 young adults (18-25 Years) with clinically diagnosed moderate to severe acne vulgaris.The inclusion criteria were Age between 18 and 25 years old and moderate to severe acne vulgaris and exclusion criteria were acne due to secondary disorders , pregnancy and lactation. The patients were divided into two groups using table of randomization: (group A: treated by 5% dapsone gel plus isotretinoin and group B: vehicle neutral gel plus isotretinoin). All patients were administered oral Isotretinoin (Roaccutan) 20 mg once a day. They received topical treatment on their face twice daily for 8 weeks.In order to supply the dapsone gel, dapsone powder was dissolved in ethanol and then prepared in gel vehicle up to 5% concentration. An objective clinical scoring (The Global Acne Assessment Score) and the number of inflamed and non-inflamed facial lesions and side effects of treatment were documented on base line and weeks 4, 8 and 12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011015509N1**
Registration date: **2014-04-07, 1393/01/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-07, 1393/01/18

Registrant information

Name
Mehrdad RakhshanPour
Name of organization / entity
Isfahan university of medical sciences.
Country
Iran (Islamic Republic of)
Phone
+98 31 1458 8136
Email address
m_rakhshan_md@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-01-18, 1391/10/29

Expected recruitment end date

2013-05-18, 1392/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 5% dapsone gel plus oral isotretinoin with oral isotretinoin alone in young patients with moderate to severe facial acne

Public title

Treatment of acne with dapsone gel plus oral isotretinoin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 25 years old; moderate to severe facial acne; absence of contraindications to treatment with tablets of isotretinoin and 5% dapsone gel. Exclusion criteria: acne secondary to other problems; pregnancy or intention to become pregnant; breastfeeding; another dermatological disease of the face; G6PD deficiency; and known hypersensitivity to dapsone or isotretinoin.

Age
From **18 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
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 placebo and actual drug 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
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave. Isfahan

City
Isfahan

Postal code

Approval date
2013-01-23, 1391/11/04

Ethics committee reference number
392090

Health conditions studied

1

Description of health condition studied
Acne Vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne Vulgaris

Primary outcomes

1

Description
Acne vulgaris lesions

Timepoint
Baseline, weeks 4, weeks 8, weeks 12.

Method of measurement
Total Acne lesion Count(TLC.) and The Global Acne Assessment Score for each patient

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 was applied on the face twice daily for 8 weeks with Isotretinoin (Roaccutan) 20 mg daily.Mode of Use and application in the study: apply twice a day, every day, for 8 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 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 period was 8 weeks and total follow up period was 12 weeks.

Category
Treatment - Drugs

2

Description
Vehicle neutral gel was applied on the face twice daily for 8 weeks with Isotretinoin (Roaccutan) 20 mg

daily.Mode of Use and application in the study: apply twice a day, every day, for 8 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 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. treatment period was 8 weeks and total follow up period was 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Dermatology Clinic

Full name of responsible person

Dr. Mehrdad Rakhshanpour

Street address

Department of Dermatology, Alzahra Hospital, Soffeh Blvd. Isfahan

City

Isfahan

2

Recruitment center

Name of recruitment center

Dermatology Clinic of Noor and Ali Asghar Hospital

Full name of responsible person

Dr. Mehrdad Rakhshanpour

Street address

Noor and Ali Asghar Hospital, Ostandari Ave. 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 Jarib Ave. 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. Mehrdad Rakhshanpour

Position

Resident of Dermatology/MD.

Other areas of specialty/work

Street address

Dermatology Group, Alzahra Hospital, Soffeh Blvd. Isfahan

City

Isfahan

Postal code

Phone

+98 31 1458 8136

Fax

Email

m_rakhshan_md@med.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, Alzahra Hospital, Soffeh Blvd. Isfahan

City

Isfahan

Postal code

Phone

+98 31 1663 3061

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. Mehrdad Rakhshanpour

Position
Resident of dermatology/MD.

Other areas of specialty/work

Street address
Dermatology Group, Alzahra Hospital, Soffeh Blvd.
Isfahan

City
Isfahan

Postal code

Phone
+98 31 1458 8136

Fax

Email
m_rakhshan_md@med.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