

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of 5% dapson 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% dapson 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% dapson 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 dapson gel, dapson 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

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##### 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% dapson gel plus oral isotretinoin with oral isotretinoin alone in young patients with moderate to severe facial acne

##### Public title

Treatment of acne with dapson 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**

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**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**

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## Person responsible for updating data

### Contact

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**City**

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**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*