

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

A Controlled clinical trial to compare the effect of Montelukast and placebo on disease symptoms and process among 45-15 year old patients with mild to moderate acne

Protocol summary

2017-06-19, 1396/03/29

Summary

This study is a prospective clinical trial to compare the effect of Montelukast 5 mg chewable tablet with placebo, on acne course and severity in 40 patients with acne, who attend Razi Skin Hospital affiliated by Tehran University of Medical Sciences. This study is a double blinded study and participants' major inclusion criteria are patients with mild to moderate acne, being at the age of 15-45 year-old who have not received antibiotics and drugs for the treatment of acne within the last 3 months. Patients with the acne caused by endocrine diseases and ones with severe and scarring acne are excluded. Based on having the inclusion criteria, patients are included in the study and divided into two groups of intervention and control (20 patients in each group). Patients in intervention group will receive Montelukast 5mg chewable tablet and Acnomis cream (tretinoin 0.25% + clindamycin) once a day and patients in control group will receive Acnomis cream (tretinoin 0.25% + clindamycin) and Placebo chewable tablet once a day for 3 months. Acne severity will be evaluated in patients using Global Acne Severity Scale and will be documented with photography before starting the treatment and then after 1 month and 3 months. The side effects of drugs will also be evaluated in each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020632402N1**

Registration date: **2017-06-19, 1396/03/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Samane Moghanlou

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 0233

Email address

smoghanlou@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Science

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Controlled clinical trial to compare the effect of Montelukast and placebo on disease symptoms and process among 45-15 year old patients with mild to moderate acne

Public title

Montelukast effect in acne treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with acne; being at the age of 15-45 years old; using antibiotic and other acne treatments for less than 3 months. Exclusion criteria: age under 14 year-old and older than 45 year-old; indication for systemic retinoid treatment; nodulocystic acne (with scar formation possibility); antibiotic treatment for more than 3 months; Hormonal related acne(polycystic ovarian disease)

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

4th Floor, No. 23, before Pour Sina St. - 16th Azad St. - Keshavarz Blvd

City

Tehran

Postal code

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1824

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Acne severity

Timepoint

Before treatment, 1 month and 3 months after treatment

Method of measurement

Acne global severity scale questionnaire

Secondary outcomes

1

Description

Drug Side effects

Timepoint

1 month and 3 months after the beginning of treatment

Method of measurement

Asking patients

Intervention groups

1

Description

Intervention group: Treatment with Montelukast 5 mg chewable tablet, once a day plus tertinoin 0.25% +and clindamycin topical cream (acnomis) applied to the whole face once a day for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Treatment with placebo chewable tablet once a day plus tertinoin 0.25% +and clindamycin topical cream (acnomis) applied to the whole face once a day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi skin hospital

Full name of responsible person

Samane Moghanlou

Street address

Razi Skin Hospital,Vahdat eslami crossroads, Vahdat eslami Street.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Room Number 206, First floor, building1, School of medicine of Tehran university of Medical Science, Poursina street, Keshavarz Blvd.

City

Tehran

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, Tehran 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

Razi skin hospital

Full name of responsible person

Samane Moghanlou

Position

Dermatology resident

Other areas of specialty/work

Street address

Vahdat eslami street

City

Tehran

Postal code

Phone

+98 912 338 3537

Fax

Email

Samane.moghanlou@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi skin hospital

Full name of responsible person

Samane Moghanlou

Position

Dermatology resident

Other areas of specialty/work

Street address

Vahdat eslami crossroad, Vahdat eslami street

City

Tehran

Postal code

Phone

00

Fax

Email

Samane.moghanlou@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Razi skin hospital

Full name of responsible person

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Phone

00

Fax

Email

Samane.moghanlou@gmail.com

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