

# 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

##### 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**

2017-06-19, 1396/03/29

##### 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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Other areas of specialty/work**

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## 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*