

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Clinical study for the evaluation of a topical formulation of Cinnamon essential oil in treatment of Acne symptoms

#### Protocol summary

##### Summary

Project goal: Evaluation of clinical efficacy of a topical formulation of Cinnamon essential oil in treating acne symptoms Design of study: Non-Randomized, Non-blind, without placebo control, Single-center, Phase 2-3 trial. a- Study group: Patients with mild to moderate acne. Major inclusion criteria: Age of 20-58 years, Mild to Moderate Acne affection, without cystic acne, having at least 15 inflamed and 15 non-inflamed acne lesions on the face. Major exclusion criteria: History of acute disease of patient or any type of sensitivity or allergy to the components of medication. Using topical anti-acne medications which include vitamin A, Alpha or Beta-hydroxy acids, Retin A, Antibiotics or benzoyl peroxide during 4 weeks before the beginning of intervention. Using oral antibiotics for treating acne during 1 month before the beginning of intervention. Using systemic isotretinoin or application of laser therapy, microdermabrasion and chemical peeling during 6 month before the beginning of intervention. Pregnant or Lactating women. Women who want to be pregnant in the next 6 month after the beginning of intervention. Patients who are exposed to long-term and direct sunlight or UV lamps, without skin protection, due to their occupation. Patients who do not follow the protocol of treatment. Sample size: 15 patients. b-Study intervention/interventions: Application of a topical formulation including Cinnamon essential oil. c- Intervention period: 8 weeks. Primary outcome or outcomes of the study: Changes in sebum production, skin erythema, Transepidermal water loss, pH, the number of comedones, and skin lesions.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016030726938N2**

Registration date: **2016-04-05, 1395/01/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-04-05, 1395/01/17

##### Registrant information

###### Name

Mahdi Vazirian

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6412 1223

###### Email address

vazirian\_m@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical study for the evaluation of a topical formulation of Cinnamon essential oil in treatment of Acne symptoms

##### Public title

Effect of topical formulation of Cinnamon essential oil in

treatment of Acne

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: Age of 20-58 years; Mild to Moderate Acne affection, without cystic acne; having at least 15 inflamed and 15 non-inflamed acne lesions on the face. Exclusion criteria: History of acute disease of patient or any type of sensitivity or allergy to the components of medication; Using topical anti-acne medications which include vitamin A, Alpha or Beta-hydroxy acids, Retin A, Antibiotics or benzoyl peroxide during 4 weeks before the beginning of intervention; Using oral antibiotics for treating acne during 1 month before the beginning of intervention; Using systemic isotretinoin or application of laser therapy, microdermabrasion and chemical peeling during 6 month before the beginning of intervention; Pregnant or Lactating women; Women who want to be pregnant in the next 6 month after the beginning of intervention; Patients who are exposed to long-term and direct sunlight or UV lamps, without skin protection, due to their occupation; Patients who do not follow the protocol of treatment.

**Age**  
From **20 years** old to **58 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **15**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran.

##### City

Tehran

##### Postal code

#### Approval date

2016-02-29, 1394/12/10

#### Ethics committee reference number

IR.TUMS.REC.1394.2104

## Health conditions studied

### 1

#### Description of health condition studied

Acne

#### ICD-10 code

L70.9

#### ICD-10 code description

Acne, unspecified

## Primary outcomes

### 1

#### Description

Skin erythema

#### Timepoint

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

#### Method of measurement

Mexameter

### 2

#### Description

pH

#### Timepoint

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

#### Method of measurement

pH-meter

### 3

#### Description

Skin hydration

#### Timepoint

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

#### Method of measurement

Corneometer

### 4

#### Description

Change in sebum production

#### Timepoint

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

#### Method of measurement

Sebumeter

## 5

### **Description**

Trans Epidermal Water Loss (TEWL)

### **Timepoint**

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

### **Method of measurement**

TEWAmeter

## 6

### **Description**

Skin marks

### **Timepoint**

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

### **Method of measurement**

Skin surface analyzer

## 7

### **Description**

Acne lesion and presence of Propionibacterium acnes bacteria

### **Timepoint**

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

### **Method of measurement**

Visiopor

## 8

### **Description**

Number of Comedones

### **Timepoint**

Before intervention, 4 weeks after the beginning of intervention and 8 weeks after the beginning of intervention

### **Method of measurement**

Clinical examination

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Cinnamon essential oil (maximum 1%) in a topical formulation will apply on acne, two times a day (morning and night), for 8 weeks

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Center of Research and Training in Skin Diseases and Leprosy

#### **Full name of responsible person**

Dr. Saman Ahmad Nasrollahi

#### **Street address**

No. 415, Nader Ave. corner, Taleghani Ave.

#### **City**

Tehran

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Dr. Mohammad Reza Hadian

#### **Street address**

Research affairs, No. 124, International Campus of Tehran University of Medical Sciences, North Mozafar Ave., Dameshq Ave., Vali Asr Ave.

#### **City**

Tehran

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

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**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Mahdi Vazirian

#### **Position**

PhD of Pharmacognosy

#### **Other areas of specialty/work**

#### **Street address**

Pharmacognosy Lab., Second Floor, New building, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

#### **City**

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+98 21 6412 1223  
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Vazirian\_m@tums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mahdi Vazirian  
**Position**  
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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*