

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical evaluation of efficacy of a topical formulation containing Ajwain 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: **IRCT2016031126938N3**

Registration date: **2016-04-08, 1395/01/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-08, 1395/01/20

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 evaluation of efficacy of a topical formulation containing Ajwain essential oil in treatment of Acne symptoms

Public title

Effect of topical formulation of Ajwain 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
2016-02-23, 1394/12/04
Ethics committee reference number
IR.TUMS.REC.1394.2063

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

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

2

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

3

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

4

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

5

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

6

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

7

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

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

Ajwain 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 buliding, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar

Ave., Enqelab Ave.

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Vazirian_m@tums.ac.ir

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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