Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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 buliding, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.
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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