

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

To investigate the effectiveness of tea tree oil gel on the treatment of mild to moderate facial seborrheic dermatitis in comparison with placebo

Protocol summary

Summary

Goal of study: The goal of this study is to investigate the effectiveness of tea tree oil gel on the treatment of mild to moderate facial seborrheic dermatitis in comparison with placebo. Study protocol: This study is a double-blind, one center, randomized vehicle-controlled clinical trial (Phase 1). Patients with seborrheic dermatitis admitted to Skin Diseases Research Center, Qazvin university of medical sciences. Inclusion criteria: patients with mild-to-moderate facial seborrheic dermatitis diagnosis, age 18 to 45 years old. Exclusion criteria: pregnant or breastfeeding women; people under 18 or over 45 years, patients with active, localized, or systemic infection, use of products for seborrheic dermatitis or systemic steroids within the last two weeks ,known allergy to lotions or moisturizers . Sample size: 27 patients in each group Intervention: The groups will be treated topically with tea tree oil gel, three times per day for one month. Intervention time: October-december 2013 Primary outcome: evaluation of seborrheic dermatitis symptoms Secondary outcome: adverse effect

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072314117N1**

Registration date: **2013-08-18, 1392/05/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name

Akram Beheshti

Name of organization / entity

Metabolic Diseases Research Center, Qazvin

University of Medical Sciences, Qazvin, Iran

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the effectiveness of tea tree oil gel on the treatment of mild to moderate facial seborrheic dermatitis in comparison with placebo

Public title

To investigate the effectiveness of tea tree oil gel on the treatment of mild to moderate facial seborrheic dermatitis in comparison with placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with mild-to-moderate facial seborrheic dermatitis diagnosis, age 18 to 45 years old.

Exclusion criteria: pregnant or breastfeeding women;

people under 18 or over 45 years, patients with active, localized, or systemic infection, use of products for seborrheic dermatitis or systemic steroids within the last two weeks ,known allergy to lotions or moisturizers .

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

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

Qazvin University of Medical Sciences Ethic Committee

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Postal code

Approval date

2012-06-19, 1391/03/30

Ethics committee reference number

28/20/5996

Health conditions studied

1

Description of health condition studied

seborrhoeic dermatitis

ICD-10 code

L21.8

ICD-10 code description

seborrhoeic dermatitis

Primary outcomes

1

Description

Improvement of seborrheic dermatitis symptoms

Timepoint

After 2 weeks intervention and after 4 weeks intervention

Method of measurement

Clinical examination and comparison with previous conditions

Secondary outcomes

1

Description

Adverse effect

Timepoint

After 2 weeks intervention and after 4 weeks intervention

Method of measurement

Clinical examination and comparison with previous conditions

Intervention groups

1

Description

Intervention group: the groups will be treated topically with tea tree oil gel, three times per day for one month.

Category

Treatment - Drugs

2

Description

Control group: Base gel without drug substances

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Clinic of Boo-Ali Sina Hospital

Full name of responsible person

Street address

Qazvin Metabolic Disease Research Center, Boo-Ali Hospital, Boo-Ali St., Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeed Asefzadeh

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahaonar blvd

City

Qazvin

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, Qazvin 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

Metabolic Diseases Research Center, Qazvin University of Medical Sciences, Qazvin, Iran

Full name of responsible person

Akram Beheshti

Position

Assistant Professor, Department of Dermatology

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