

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of therapeutic effects of Tea Tree Oil nanoemulsion gel containing adapalene with commercial form of adapalene gel for the treatment of acne vulgaris

Protocol summary

Summary

The aim of this study was to compare the therapeutic effect of topical Tea Tree Oil nanoemulsion containing adapalene, with commercially available adapalene gel in treatment of mild to moderate Acne Vulgaris. In this regards, randomized double-blind clinical trial, 160 patients with Acne Vulgaris will be allocated into two groups. Pregnant and breast feeding women, children younger than 15 years, patients with severe acne or previous anti-acne therapy in recent 2 weeks and patients using acne-inducing drugs will be excluded. Groups will be prescribed to two groups under study for a 12-week period. Inflammatory and non-inflammatory lesions will be counted, and the side effects assessed and recorded monthly during the study period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090223864N1**

Registration date: **2015-10-19, 1394/07/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-19, 1394/07/27

Registrant information

Name

Amir Amani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 218899111824

Email address

aamani@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of Tea Tree Oil nanoemulsion gel containing adapalene with commercial form of adapalene gel for the treatment of acne vulgaris

Public title

The treatment of Acne Vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of mild to moderate Acne Vulgaris (up to 10 comedons, papular and/or pustular lesions). Exclusion criteria: pregnant and lactating women, children younger than 15 years old, severe cases of acne (existence of nodules and cysts), receiving anti acne during two weeks prior to study, taking acne creating drugs such as oral or local steroids, spirinolactone, finasteride. Patient with diabetes mellitus, endocrine disorder.

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-07-29, 1394/05/07

Ethics committee reference number

94-01-87-28505-159333

Health conditions studied

1

Description of health condition studied

acne vulgaris

ICD-10 code

L70

ICD-10 code description

acne vulgaris

Primary outcomes

1

Description

Inflammatory and noninflammatory lesions

Timepoint

Baseline and after 4,8, and 12 weeks

Method of measurement

counting lesions using manual lens

Secondary outcomes

1

Description

side effect

Timepoint

Baseline and after 4, 8, and 12 weeks

Method of measurement

case report form

Intervention groups

1

Description

Topical tea tree oil nanoemulsion loaded 0.1% adapalene gell, one times daily on the clean skin for 3 months

Category

Treatment - Drugs

2

Description

Topical adapalene gell 0.1%, one times daily on the clean skin for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Amir-Hoshang Ehsani

Street address

Vahdat Eslami St., Tehran ,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Qods Street; Tehran, Iran

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

Roqiye Najafi-Taher

Position

Ph.D Candidate of Medical Nanotechnology

Other areas of specialty/work**Street address**

Eastern side of Tehran University, 88, Italia St, The School of Advanced Technologies in Medicine (SATiM), Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8899 1118

Fax**Email**

r-najafitaher@razi.tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical sciences

Full name of responsible person

Dr. Amir Amani

Position

Associate Professor

Other areas of specialty/work**Street address**

Eastern side of Tehran University of Medical sciences, 88E, Italia St, The school of Advance Technologies in Medicine(SATiM), Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8899 1117

Fax

+98 21 8899 1117

Email

aamani@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Roqiye Najafi-Taher

Position

Ph.D Candidate of Medical Nanotechnology

Other areas of specialty/work**Street address**

Eastern side of Tehran University, 88, Italia St, The School of Advanced Technologies in Medicine (SATiM), Tehran, Iran

City

Tehran

Postal code**Phone**

00

Fax**Email**

r-najafitaher@razi.tums.ac.ir

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