Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of theraputic 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

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Name of organization / entity
Tehran University of Medical Sciences
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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 theraputic 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, spirnolactone, 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 gel, one times daily on the clean skin for 3 months

Category
Treatment - Drugs

2

Description
Topical adapalene gel 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

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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

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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