

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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*