

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Aloe vera topical gel combined with tretinoin in treatment of mild and moderate acne vulgaris: a randomized, double-blind, placebo controlled trial

Protocol summary

Summary

The aim of this study is to compare the efficacy and safety of the combination of tretinoin cream (0.05%) and Aloe vera topical gel (50%) with tretinoin and vehicle on mild to moderate acne vulgaris patients. The patients will not be satisfied with their previous acne therapies. Patients were excluded if they had an uncontrolled systemic disease; had received topical antiacne therapy two months before or during the study or any systemic therapy with antibiotics 30 days before or during the study. The randomized, double blind, prospective, placebo-controlled 8-week trial will evaluate inflammatory and noninflammatory lesion counts and tolerability in 60 subjects with mild to moderate acne vulgaris (Global Acne Grading System scale).

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2012070810203N2**

Registration date: **2012-08-09, 1391/05/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Majid Saeedi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3082

Email address

msaeedi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-04-03, 1389/01/14

Expected recruitment end date

2012-03-08, 1390/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aloe vera topical gel combined with tretinoin in treatment of mild and moderate acne vulgaris: a randomized, double-blind, placebo controlled trial

Public title

Effect of Aloe vera gel on acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the score of acne was determined based on GAGS scale and patients with mild to moderate acne vulgaris enter to study; and a urinary pregnancy test was performed; the cases have not received any medication. Exclusion criteria: Patients with an uncontrolled systemic disease; patients had received topical antiacne therapy two months before or during the study or any systemic therapy with antibiotics 30 days before or during the study; were known to be allergic or

sensitive to any of the study medications or their components; had previously been treated with systemic retinoids; or were pregnant, or planning to become pregnant, and lactating.

Age

From **11 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

1

Registry name

Traditional and complementary research center

Secondary trial Id

90-129

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences ethics committee

Street address

Moallem sq., Chancellor of research

City

Sari

Postal code

Approval date

2012-02-08, 1390/11/19

Ethics committee reference number

90-129

Health conditions studied

1

Description of health condition studied

Mild to moderate acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

acne vulgaris

Primary outcomes

1

Description

lesion count

Timepoint

0, 2, 4, 8 th. week

Method of measurement

lesion scoring

2

Description

adverse reactions (scaling, oedema, erythema, burning, and itching)

Timepoint

2, 4, 8 th. week

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Tretioin cream once a day (at night) and Aloe vera gel 50% (twice in day)

Category

Treatment - Drugs

2

Description

Tretinoin cream once a day (at night) and Placebo (twice in day) for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dermatology, Tooba Clinic, Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

18th. km of Khazar road, Faculty of Pharmacy, P.O.Box: 48175-861

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor of Research, Mazandaran University of
Medical Sciences

Full name of responsible person

Prof. A. Enayati

Street address

Moallem sq., Chancellor of Research Building

City

Sari

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Chancellor of Research, Mazandaran 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

Department of pharmaceutics

Full name of responsible person

Majid Saeedi

Position

Professor

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