

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of Spironolactone nano emulgel (1%) effect on skin characteristics and treatment of mild to moderate acne vulgaris in comparison with spironolactone gel 5%

Protocol summary

Summary

The nano particles (SLN and NLC) of Spironolactone will be prepared and the emulgel 1% will formulate by suitable polymer. The characteristics of nano particles (particle size, zeta potential and entrapment efficacy) will evaluate. The effect of spironolactone nano emulgel will be evaluated on acne in comparison with simple spironolactone gel 5%. The patients with mild to moderate acne will included in study. The samples which received any antibiotic in last 3 months will excluded from study. 30 patients will included in every group. The case group will receive Lavander nano emul-gel, and control group will receive tretinoin cream for 2 months. The skin lesions (comedone, papule and pustules in 0, 4, and 8m weeks) will be counted. The skin characteristics like sebum excretion, hydration, elasticity, redness and melanin content will define too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051010203N6**

Registration date: **2015-05-22, 1394/03/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-22, 1394/03/01

Registrant information

Name

Majid Saeedi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

msaeedi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

chancellor of research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-05-10, 1394/02/20

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Spironolactone nano emulgel (1%) effect on skin characteristics and treatment of mild to moderate acne vulgaris in comparison with spironolactone gel 5%

Public title

Effect of Spironolactone nano-emulgel on acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with mild to moderate acne, defined as a score of 1 to 30 on the global acne grading system (GAGS) scale, who were not satisfied with their previous acne therapies participated in the study after giving written informed consent Exclusion criteria: 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, OCP, and spironolactone 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; had a skin disease that might interfere with the diagnosis or evaluation of their hyperpigmentation; or were pregnant, or planning to become pregnant, and lactating.

Age

From **11 years** old to **45 years** old

Gender

Both

Phase

2

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**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Chancellor of Research, Mzandaran University of Medical Sciences

Street address

Moallem square

City

Sari

Postal code**Approval date**

2013-02-19, 1391/12/01

Ethics committee reference number

91261

Health conditions studied**1****Description of health condition studied**

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes**1****Description**

skin lesion

Timepoint

0, 4, and 8 weeks

Method of measurement

observation

Secondary outcomes**1****Description**

sebum excretion

Timepoint

0, 4, 8 weeks

Method of measurement

sebometer

Intervention groups**1****Description**

case: nano emulgel of spironolactone 1%, two times in day (BID) as topical, and for 2 months

Category

Treatment - Drugs

2**Description**

control: spironolactone gel 5%. The preparations will be administered topically, two times in day and for two months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Boo Ali Hospital

Full name of responsible person

Dr. Majid Saeedi

Street address**City**

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moallem square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research

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

Faculty of Pharmacy

Full name of responsible person

Majid Saeedi

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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