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 Spironolactonel 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 recive 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)

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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 Exclusioncriteria: 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
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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

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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