Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of spironolactone nanostructured lipid carriers coated with chitosan and clindamycin solution co-treatment effect on severity of mild to moderate acne vulgaris

Protocol summary

Study aim
Determination of spironolactone lipid nanoparticles coated by chitosan on acne

Design
The eligible patients will divided in two groups randomly and will receive every preparation twice in day. The number and kind of skin lesions will evaluate during 8 weeks.

Settings and conduct
The acne grade will define based on lesion count. The patient will receive topical preparations during 8 weeks. The patients, prescriber and evaluator are blind. The patients will evaluate at zero time, 2, 4, and 8 weeks. All of the patients will receive topical antibiotic.

Participants/Inclusion and 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, Patients which received topical anti-acne therapy two months before or during the study or any systemic therapy with antibiotics, OCP, retinoid, and spironolactone before or during the study, patients were excluded if they had other disease; pregnant, or planning to become pregnant women, lactating, and allergic or sensitive patients to preparation will not include to study.

Intervention groups
Intervention group will receive clindamycin solution 2% and topical preparation containing coated spironolactone nanoparticles. Control group will receive clindamycin solution 2% and placebo.

Main outcome variables
Non-inflammatory lesions (comedones); Inflammatory lesions (papule and pustule)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120707010203N11**
Registration date: **2021-01-11, 1399/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-11, 1399/10/22**
Update count: **0**

Registration date
2021-01-11, 1399/10/22

Registrant information
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Majid Saeedi
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of spironolactone nanostructured lipid carriers coated with chitosan and clindamycin solution co-treatment effect on severity of mild to moderate acne vulgaris

Public title

Evaluation of spironolactone nanoparticles coated with chitosan topical preparation effect 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. Patients which received no previous acne therapies participated in the study, or have not received any treatment before this study

Exclusion criteria:

Patients which received topical anti-acne therapy two months before or during the study or any systemic therapy with antibiotics, OCP, retinoid, and spironolactone before or during the study Patients were excluded if they had other disease; Pregnant, or planning to become pregnant women Lactating

Age

From **13 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control using simple randomization and patients will divide to intervention or placebo group based on their code. Randomization list will be done by online tool (https://www.random.org/lists) and sealed envelope will used for concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

All of patients will received clindamycin 2% solution in two groups. The patients will receive topical preparation of spironolactone nanoparticles 1% in case group, and control group will receive placebo in similar packaging. Topical preparation and placebo have certain code and clinical evaluator has no information about them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology building, Moallem sq., Sari, Iran

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Mazandaran

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4817844718

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.MAZUMS.REC.1399.691

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

No. of lesions

Timepoint

At the beginning of study (time zero) and 2, 4 and 8 weeks after treatment

Method of measurement

clinical evaluation

Secondary outcomes

1

Description

Lesion kind (inflammatory or non-inflammatory)

Timepoint

At the beginning of study (time zero) and 2, 4 and 8 weeks after treatment

Method of measurement

Clinical evaluation

Intervention groups

1

Description
Intervention group: Topical preparation containing spironolactone nanoparticles (NLC) coated by chitosan (1%), will prepared as emulgel. The preparation will package and add code label , after physicochemical and microbial control. The patients will apply preparation twice in day for 8 months on skin lesions. They will receive clindamycin 2% solution as main treatment in this period of time too.

Category
Treatment - Drugs

2

Description
Control group: Topical placebo will prepared. The preparation will package and add code label , after physicochemical and microbial control. The patients will apply placebo twice in day for 8 months on skin lesions. They will receive clindamycin 2% solution as main treatment in this period of time too.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Boo-Ali Hospital

Full name of responsible person
Prof. Zohreh Haj heydari

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Dermatology clinic, Boo-Ali Hospital, Pasdaran Blvd., Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Mazandaran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Majid Saeedi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
it is secret

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available