

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluate the efficacy of nano lipid carrier drug delivery system containing tretinoin

Protocol summary

Study aim

Evaluate the efficacy of nano lipid carrier drug delivery system containing tretinoin

Design

In this study, 20 patients with moderate to severe acne with entry requirements referring to the center of the skin and leprosy are selected. In these participants, one side of the face is selected for use of the nano-lipid tretinoin and the opposite side for the typical cream of tretinoin.

Settings and conduct

the study conducted on all patients with moderate to severe acne vulgaris referred to the center of research and training in skin diseases and leprosy. the study was a randomized parallel single blind (patient) study. patients in both treatment groups will use topical formulation with similar physical appearance and packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria Aged between 12 to 40 years 10 -50 acne lesions No change in diet and life style during the study Signed informed consent voluntarily and knowingly
Exclusion criteria Long-time exposure to UV radiation History of sensitivity to topical anti acne drug therapy Use of topical anti acne drug therapy including AHA, BHA, benzyl peroxide, vitamin A, retin-A, antibiotics within one month prior to the study Pregnancy / breastfeeding History of systemic antibiotics for acne treatment within one month prior to the study

Intervention groups

Rubbing nano lipid of tretinoin into the acne lesions on one side of the face once a day for 8 weeks.
Control: Rubbing the tretinoin cream into the lesions area on the opposite face once a day for 8 weeks

Main outcome variables

Evaluation of the improvement of based on the Global Acne Grading System with comparison of the photos taken from the location of the lesions at zero time and then at 4th and 8th weeks after treatment. Secondary

outcome: (a) local dry skin through physical examination at 4th and 8th weeks after treatment; (b) local erythema through physical examination at 4th and 8th weeks after treatment; (c) local skin irritation through taking history of the patient at 4th and 8th weeks after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N2**

Registration date: **2018-01-03, 1396/10/13**

Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**

Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-03, 1396/03/13

Expected recruitment end date

2017-10-29, 1396/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the efficacy of nano lipid carrier drug delivery system containing tretinoin

Public title

Effect of tretinoin nano lipid on acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Aged between 12 to 40 years 2. 10 -50 acne lesions 3. No change in diet and life style during the study 4. Signed informed consent voluntarily and knowingly

Exclusion criteria:

Long-time exposure to UV radiation History of sensitivity to topical anti acne drug therapy Use of topical anti acne drug therapy including AHA, BHA, benzyl peroxide, vitamin A, retin-A, antibiotics within one month prior to the study Pregnancy / breastfeeding History of systemic antibiotics for acne treatment within one month prior to the study

Age

From **12 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

By using the random numbers table

Blinding (investigator's opinion)

Single blinded

Blinding description

the study was a randomized parallel single blind (patient) study. patients in both treatment groups will use topical formulation with similar physical appearance and packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pharmaceutical sciences branch,Ethic committee of Islamic azad university

Street address

Yakhchal street - Islamic Azad University Of Pharmaceutical Sciences Branch

City

Tehran

Province

Tehran

Postal code

19395-6466

Approval date

2016-01-30, 1394/11/10

Ethics committee reference number

IR.TUMS.REC.1394.1771

Health conditions studied

1

Description of health condition studied

acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Modified acne severity index

Timepoint

Beforeintervention, one monthlater ,two month after intervention

Method of measurement

MPA580

Secondary outcomes

1

Description

Skin PH

Timepoint

Before and after 4 and 8 weeks

Method of measurement

MPA580

2

Description

Skin sebum

Timepoint

Before and after 4 and 8 weeks

Method of measurement

MPA580

3

Description

Skin melanin and erythem

Timepoint

Before and after 4 and 8 weeks

Method of measurement

MPA580

4

Description

Transepidermal water loss

Timepoint

Before and after 4 and 8 weeks

Method of measurement

MPA580

5

Description

Hydration

Timepoint

Before and after 4 and 8 weeks

Method of measurement

MPA580

6

Description

Size and value of acne

Timepoint

Before and after 4 and 8 weeks

Method of measurement

Visiopor

Intervention groups

1

Description

Intervention group: Administration of tretinoin Nanolipid in Patients with Moderate to Severe Acne

Category

Treatment - Surgery

2

Description

Control group: Administration of tretinoin Cream in Patients with Moderate to Severe Acne

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research and Training in skin Diseases and Laprosy

Full name of responsible person

Saman Ahmad Nasrollahi

Street address

415,Taleghani Ave,Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

samannasrol@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based company

Full name of responsible person

Najva Kashani

Street address

No. 415, Taleqni Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416613675

Email

samannasrol@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based company

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

Center For Research And Training In Skin Diseases
And Leprosy

Full name of responsible person

Saman Ahmad Nasrollahi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 415, Taleqni Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

samannasrol@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza firooz

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

No. 415, Taleqni Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

firozali@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic azad university of pharmaceutical science

Full name of responsible person

Zohre Sartipi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Yakhchal street - Islamic Azad University Of
Pharmaceutical Sciences Branch

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 212264005155

Fax**Email**

zohre.sartipi@yahoo.com

Web page address

<http://fa.iaups.ac.ir/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available