

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Study of clinical effects of solid lipid nanoparticles Isotretinoin in treatment of acne

Protocol summary

Summary

The purpose of this study is to determine the characteristics and clinical effects of solid lipid nanoparticles (SLN) containing Isotretinoin in treatment of acne and compare with the commercial gel of Isotretinoin (Isotrex). In this study, SLN prepared using different lipids and their characteristics are determined, then 30 patients with moderate acne, who have inclusion and exclusion criteria, are chosen. A group of patients (group1) were treated with Isotretinoin topical gel available in the market with Hydroalcoholic solution of clindamycin 2% for 8 weeks and another group (group2) were treated with topical SLN containing Isotretinoin with equal concentrations and 2% clindamycin solution for 8 weeks. Then count the number of inflammatory and non-inflammatory lesions in the start of treatment, second, fourth, sixth and eighth weeks and the report of recovery percent based on seven degree was done; 0=completely recovered, 1 = almost recovered (~ 90%), 2 = remarkable improvement (~ 75%), 3 = moderate improvement (~ 50%), 4 = poor recovery (~ 25%), 5 = No difference and 6 = became worse; that if the further improvement was more than 50% effective, reported. Also the sensitivity of prepared products and marketed form will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203283862N9**

Registration date: **2013-05-10, 1392/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-10, 1392/02/20

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

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banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Nano Technology Research Center, Mashhad University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of clinical effects of solid lipid nanoparticles Isotretinoin in treatment of acne

Public title

Evaluation of solid lipid nanoparticles containing Isotretinoin in treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Acne vulgaris patients with grade 2 and 3 based on Investigator Global Assessment; No receiving topical treatment of acne from 4 weeks before this

regimen. exclusion criteria: Androgenic acne; Acne due to drugs or cosmetics; Adrenal or Hormonal disorders.

Age

From **13 years** old to **30 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashad University of Medical Sciences

Street address

Central Building of Mashad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2011-04-30, 1390/02/10

Ethics committee reference number

89940

Health conditions studied

1

Description of health condition studied

Acne Vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne

Primary outcomes

1

Description

inflammatory and non-inflammatory lesions

Timepoint

Biweekly after starting treatment

Method of measurement

Observation and calculating of elementary lesions based on photographic image

Secondary outcomes

1

Description

evaluation of side effects like skin irritation , erythema , skin dryness.pruritus

Timepoint

Biweekly

Method of measurement

Observation and severity scoring from + to +++

Intervention groups

1

Description

Control group: receiving of 0.05% isotretinoin gel (isotrex); made in Irland. once a day for 8 weeks

Category

Treatment - Drugs

2

Description

Interventional group:receiving solid lipid nanoparticles (SLNs) containing 0.05% isotretinoin once a day for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Quem Hospital, Department of Dermatology, research center for skin diseases and cutaneous leishmania

Full name of responsible person

Dr Pouran Layegh

Street address

Department of Dermatology, Qaem hospital, Ahmad Abad street.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nano Technology Research Center,Mashhad
University of Medical Sciences

Full name of responsible person

Dr Shiva Golmohamadzadeh

Street address

Buali(Avicenna) research Institute, Buali square

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Nano Technology Research Center,Mashhad 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**

Nano Technology Research Center and faculty of
pharmacy

Full name of responsible person

Danial Bagheri

Position

students of pharmacy

Other areas of specialty/work**Street address**

faculty of pharmacy

City

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bagherid851@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Pharmacy, Mashhad University of medical
Sciences.

Full name of responsible person

Dr Shiva Golmohamadzadeh.

Position

Assistant professor

Other areas of specialty/work**Street address**

Faculty of Pharmacy, Vakil Abad Blvd., Opposite
Mellat park.

City

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Research center for skin diseases and cutaneous
leishmaniasis

Full name of responsible person

Akram sadat Momenzadeh

Position

of sciences, biologist

Other areas of specialty/work**Street address**

Research center for skin diseases and cutaneous
leishmaniasis,office bulding, Ahmad abad street,
Ghaem hospital.

City

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Fax**Email**

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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