

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

##### Email address

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**

Mashhad

**Postal code****Phone**

+98 51 1882 3255

**Fax****Email**

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**

Mashhad

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+98 51 1711 2611

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golmohamadzadehsh@mums.ac.ir

**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**

Mashhad

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+98 51 1841 0135

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src@mums.ac.ir

**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*