Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of isotretinoin plus NB-UVB in the treatment of psoriasis vulgaris

Protocol summary

Summary

Psoriasis vulgaris is one the commonest chronic plaque type diseases of the skin in Iran and the world that causes considerable morbidity in patients. One of the systemic treatments is retinoid that acitretin in this group is usually used. One of the side effects of acitretin is teratogenicity till 2 years after stopping it. Since the teratogenicity of isotretinoin remains only 1 month after stopping, if it improves psoriasis vulgaris considerably, it can be used instead of acitretin in the ages of reproduction in females. In this study, the patients with psoriasis vulgaris that are candidates for phototherapy will be chosen and then are randomly divided into 2 groups as intervention and control group. The cases in intervention group are taken isotretinoin (0.5mg/kg) and the controls are taken placebo for 2 weeks and after that NB-UVB is added to treatments in both ones for other 12 weeks. In the regular examinations (First visit, 4 weeks, 10 weeks, and 14 weeks after starting therapy) PASI is calculated for each one and then are compared between groups to determine the efficacy of isotretinoin in the treatment of psoriasis vulgaris.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812213543N1**
Registration date: **2010-04-24, 1389/02/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Somayeh Khezri

Name of organization / entity

Razi hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5560 9951

Email address

mortazma@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Tehran University of Medical Sciences, Behestan Darou (P.J.S)

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of isotretinoin plus NB-UVB in the treatment of psoriasis vulgaris

Public title

The efficacy of isotretinoin plus NB-UVB in the treatment of psoriasis vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic plaque type psoriasis (psoriasis vulgaris) who are candidates for phototherapy Exclusion criteria: female patients who do not have a safe contraception or want to become pregnant in less than 1 month, patient with abnormal

lipid profile tests, liver function tests and ANA

Age
From **15 years** old to **90 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor for Research of Tehran University of Medical Sciences

Street address
Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg, Poursina st.

City
Tehran

Postal code
1417613151

Approval date
2008-06-26, 1387/04/06

Ethics committee reference number
333

Health conditions studied

1

Description of health condition studied
Psoriasis vulgaris

ICD-10 code
L40.0

ICD-10 code description
psoriasis vulgaris

Primary outcomes

1

Description
Improvement of severity of psoriasis vulgaris

Timepoint
First visit, 4 weeks, 10 weeks, 14 weeks after starting therapy

Method of measurement
PASI score

Secondary outcomes

1

Description
Complications (nausea, pruritus, erythrodermia)

Timepoint
First visit, 4 weeks, 10 weeks, and 14 weeks after starting therapy

Method of measurement
clinical examination

Intervention groups

1

Description
Isotretinoin (0.5mg/kg) for 2 weeks then NB-UVB for 12 weeks

Category
Treatment - Drugs

2

Description
Placebo for 2 weeks then NB-UVB for 12 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Somayeh Khezri

Street address
Razi Hospital,Vahdat_e_eslami st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behestan Darou (P.J.S)

Full name of responsible person

Bahareh Raoof

Street address

Behestan Darou (P.J.S), 5th floor, Soraya Bldg., Pardis st., Mollasadra Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Behestan Darou (P.J.S)

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Research department of medical school of Tehran University of Medical Sciences

Full name of responsible person

Dr.Shahin Akhound Zadeh

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Research department of medical school of Tehran University of Medical Sciences,205th room,1st floor,Education Bldg.,Poursina st.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research department of medical school of Tehran University of Medical Sciences

Proportion provided by this source

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

Razi Hospital

Full name of responsible person

Somayeh Khezri

Position

Resident of dermatology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Razi Hospital

Full name of responsible person

Hossein Mortazavi

Position

Associate Professor of Dermatology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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Other areas of specialty/work

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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