

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.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behestan Darou (P.J.S)
Full name of responsible person
Bahareh Raof
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
Street address
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
Street address
Razi Hospital, Vahdat_e_eslami st.
City
Tehran
Postal code
1199663911
Phone
00982155609951, 00982155609952,
00982155609953
Fax
00982155620300, 00982155169650
Email
khezri@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Razi Hospital
Full name of responsible person
Hossein Mortazavi
Position
Associate Professor of Dermatology
Other areas of specialty/work
Street address
Razi Hospital, Vahdet_e_eslami st.
City
Tehran
Postal code
1199663911
Phone
00982155609951,00982155609952,0098215560995
3
Fax
+98 21 5516 9650
Email
motazma@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Razi Hospital
Full name of responsible person
Somayeh Khezri
Position
Resident of dermatology
Other areas of specialty/work
Street address
Razi Hospital, Vahdate eslami st.
City
Tehran

Postal code

1199663911

Phone

00982155609951, 00982155609952,
00982155609953

Fax

00982155620300, 00982155169650

Email

khezri@razi.tums.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