

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of adding Vitix gel on vitiligo lesions treating with NB-UVB phototherapy in patients referring to dermatology clinic of Quaem hospital

Protocol summary

Summary

The aim of this study is to compare treatment outcome of using Vitix® gel combination with NB-UVB versus NB-UVB alone in vitiligo patients referring to dermatology clinic of Quaem hospital. After explaining the objectives and methods of study and taking written consent patients older than 12 years with bilateral symmetrical vitiligo lesions distributed on face or limbs that involving more than 10% of body surface and not be pregnant or lactating or history of photosensitivity is enrolled. Each patient will be as his/her own control as while NBUVB phototherapy is administered on both sides of the body whereas Vitix ® gel is applied on just one side. The gel is applied 15-30 minutes before receiving NBUVB phototherapy which would administered three times per week on non consecutive days for 40 sessions or approximately 4 months. Selection of lesions for receiving vitix gel would be randomized for left or right side of the body. Serial photographs will taken by a single dermatologist who is blinded to using vitix gel on which side of body lesions and visit the cases monthly and calculate the repigmentation score according to a certain classification of proposal. At the end, the improvement results and side effects would be compare with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011216955N2**

Registration date: **2015-12-13, 1394/09/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-13, 1394/09/22

Registrant information

Name

Pouran Layegh

Name of organization / entity

department of dermatology, Ghaem hospital, Mashhad, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2015-03-13, 1393/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of adding Vitix gel on vitiligo lesions treating with NB-UVB phototherapy in patients referring to dermatology clinic of Quaem hospital

Public title

Evaluation of adding Vitix gel on vitiligo lesions treating with NB-UVB phototherapy in patients referring to

dermatology clinic of Quaem hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Bilateral symmetrical lesions distributed on face or limbs that involving more than 10% of body surface; age>12 years; who had signed a written informed consent. exclusion criteria: pregnancy; breast feeding; any history of previous hypersensitivity to Vitix gel; having skin malignancy; history of immunosuppression or taking immunosuppressive drugs; any contraindications for phototherapy; previous treatment with phototherapy from 3 months ago; history of photosensitivity; history of psychologic disorders

Age

From **12 years** old to **75 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)

Not 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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

910996

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Lesion improvement based on amount of repigmentation

Timepoint

Monthly for 4 months

Method of measurement

Calculation the repigmentation score according to a certain classification

Secondary outcomes

1

Description

Side effects

Timepoint

Monthly

Method of measurement

Based on history, physical examination and observation of the patient

Intervention groups

1

Description

Intervention group: NB-UVB phototherapy was administered on lesions of both sides of the body, three times per week on non consecutive days for 40 sessions or 4 months.

Category

Treatment - Drugs

2

Description

Control group: Each patient acted as his/her own control as while NB-UVB phototherapy was administered on lesions of both sides of the body whereas Vitix® gel (ACM, France) was applied on just one side of the body. The gel was applied 15-30 minutes before receiving NB-UVB phototherapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Quaem Hospital

Full name of responsible person

Dr Poursan Layegh

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Department of dermatology, Quaem hospital, Ahmad Abad Street

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Poursan Layegh

Position

Associate professor of dermatology

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Mashhad

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

Yes

Title of funding source

Vice Chancellor for Research of 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Poursan Layegh

Position

Associate Professor of Dermatology

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

Health School

Full name of responsible person

Mahboobe Akhlaghi

Position

Master of Science student of Biostatistic

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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