Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of topical piperine combined with narrow band UVB on vitiligo treatment: A clinical trial study

Protocol summary

Summary

Objectives: To compare the effect of topical piperine combined with narrow band UVB on vitiligo treatment with narrow band UVB alone. Design: Double-blind randomized clinical trial Setting and conduct: In this double-blind randomized clinical trial, patients with vitiligo in the facial region referring to Loghman Hakim and Shohada-e-Tajrish hospitals during 2014 to 2016 were invited for participation. Included subjects will be randomly assigned to the two treatment and placebo groups. Participants: Inclusion criteria included patients with facial vitiligo. The exclusion criteria were as follows: a history of an autoimmune disease such as alopecia areatea, diabetes, Addison's disease, pernicious anemia, Graves' disease, Hashimoto's thyroiditis, systemic lupus erythematosus, and a history of treatment with NB-UVB in the last two weeks, or a history of the use of topical medications for at least 2 weeks prior to the study. Accordingly, a total of 63 patients were selected as the sample population for this study and randomly assigned to two groups of placebo (28 subjects) and piperine (35 subjects). Intervention: The case and control groups participated in this study will be treated by topical piperine and placebo respectively for three months. It is worth noting that the standard phototherapy treatment (NB-UVB) will be given in both groups during this time. Piperine solution (1%) will be prepared by dissolving the piperine (with 95% purity, provided from Bioprex Co., India) in a solvent mixture [dimethyl sulfoxide (DMSO): isopropyl alcohol and glycerol] (20: 80). Patients in both groups will undergo NB-UVB phototherapy by Waldman UV 7001 German device for three months, every other day. The energy of the device will be set on 0.05 Joules at the first session and 0.05 Joules will be added to each session to attain a maximum level of 2 Joules and then this energy will be kept constant for further procedure. Main outcome measure: The level of repigmentation scored on a scale of 0 to 100 by the subjects along with two blinded dermatologists will be the main outcome measure. Score 0 means full depigmentation, and 100 is equal to normal skin. Evaluations will be conducted at one, two and three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061527802N2**
Registration date: **2017-07-03, 1396/04/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-03, 1396/04/12

Registrant information

Name

Anoosh Shafiee

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8807 2043

Email address

anooshshafiee@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of topical piperine combined with narrow band UVB on vitiligo treatment: A clinical trial study

Public title
Combination therapy in vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of facial vitiligo Exclusion criteria: history of alopecia areatea; diabetes; Addison's disease; pernicious anemia; Graves disease; Hashimoto’s thyroiditis; systemic lupus erythematosus; history of treatment with NB-UVB in the past two weeks; history of applying topical medications in the past 2 weeks prior to the study

Age
No age limit

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)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of dermatology research center, Shohada-E Tajrish Hospital

Street address
Dermatology research center, Shohada-E Tajrish Hospital, Tajrish Square, Tehran

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
94/192

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Repigmentation

Timepoint
Every month

Method of measurement
Objective evaluation by two blinded Dermatologists

Secondary outcomes

1

Description
Patients satisfaction

Timepoint
After four months

Method of measurement
Objective score given by the patient on a scale of 0-10

2

Description
Side effects of the treatment

Timepoint
Every month

Method of measurement
History taking and physical examination

Intervention groups

1

Description
Treatment with NBUVB plus a topical ointment as the placebo

Category
Placebo

2

Description
Treatment with NBUVB plus local application of Piperine

solition

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Shohada-E Tajrish hospital

Full name of responsible person

Anoosh Shafiee

Street address

Tajrish Square

City

Tehran

2

Recruitment center

Name of recruitment center

Dermatology Clinic of Loghman Hakim hospital

Full name of responsible person

Anoosh Shafiee

Street address

Dermatology Ward, Loghman Hakim Hospital, South Kargar St., Makhsoos Crossroad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

Street address

3rd Floor, Faculty of Medicine, Evin, Shahid Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research, Shahid Beheshti 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

Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Anoosh Shafiee

Position

MD, Dermatology resident

Other areas of specialty/work

Street address

Dermatology Ward, Loghman Hakim Hospital, South Kargar St., Makhsoos Crossroad

City

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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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