Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the efficacy of NBUVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

Protocol summary

Study aim

Determination of efficacy of NBUVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

Design

clinical trial with control group, Community based, Prospective study, randomized

Settings and conduct

This is a randomized clinical trial that was conducted in 1397 and 1398 on patients referred to the Al-Zahra Hospital and Espasadana Laser Center in Isfahan. In this study, a number of patients with refractory vitiligo who were referred to the Al-Zahra and Espadana Laser Center for NBUVB were selected randomly and after receiving consent to participate in the study, a group of patients undergoing treatment With NBUVB and the other group treated with NBUVB and needling with intalesional cynacthen once a week for three months and then grade of repigmentation evaluated in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients with refractory vilitigo with less than 50% skin lesion 2-patches with dimensions of 1-8 cm in two-sided form 3-inactivity of disease during 6 last months exclusion criteria: 1-segmental vitiligo 2-activity of disease during 6 last months

Intervention groups

In this study, two groups of 34 patients are be studied. First group are being treated with photo therapy and the other one are being treated with photo therapy and needling with intralesional cynacthen.

Main outcome variables

A new way to treat vitiligo with the least side effects and high effectiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190515043600N1**
Registration date: **2019-05-23, 1398/03/02**
Registration timing: **retrospective**

Last update: **2019-05-23, 1398/03/02**
Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Hossein Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5222 0849

Email address

farmanihossein@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison between the efficacy of NBUVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

Public title
Effect of Needling with intralesional synacthen injection in treatment of vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with refractory vitiligo with less than 50% skin leison patches in the size of 1-8 cm in two-sided form Inactivity of disease during the last 6 months
Exclusion criteria:
Segmental vitiligo Activity of vitiligo in the last 6 months
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, two groups of 34 people are studied. After getting informed consent from the patient، treatment begins and patient's treatment process is evaluated.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of medical science, Hezarjarib Ave
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Approval date
2019-05-05, 1398/02/15
Ethics committee reference number
IR.MUI.MED.REC.1398.073

Health conditions studied

1

Description of health condition studied
vitiligo
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Grade of Repigmentation
Timepoint
At the beginning of the study and three months later
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Vitiligo skin lesions
Timepoint
ابتدای مطالعه و 3 ماه بعد
Method of measurement
Percentage

Intervention groups

1

Description
Intervention group: NB-UVB Photo therapy and Needling with Intraesional Synacthen Injection
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
مرکز جراحی پلاستیک و لیزر اسپادانا
Full name of responsible person
دکتر علی اصیلیان
Street address
Golshan Alley, Mohtasham Kashani Ave, Hakim Nezami Ave
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Email
info@spadanalaser.ir
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
دکتر شقایق حق جوی جوانمرد
Street address
Isfahan University of Medical Sciences, Hezarjarib Ave
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8174673461
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+98 31 3668 0048
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
حسین فرمانی
Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
medical student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data includes patient information and treatment trends and photographs during treatment.
When the data will become available and for how long
1year after article publishing
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Research
From where data/document is obtainable
Email: farmanihossein@yahoo.com
What processes are involved for a request to access data/document
The coordination will be done during correspondence.
Comments