

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Intense Pulsed Light in Treatment of Nevus Spilus in in patients attending dermatology clinic of razi hospital

Protocol summary

Summary

I Few reports about nevus spilus treatment using intense pulsed light have been published. The aim of current study was to evaluate efficacy and safety of nevus spilus treatment with an intense pulsed light device (Palomar Max-G Intense Pulsed Light). Patients with diagnosed nevus spilus confirmed via histopathology, will be treated by an intense pulsed light source using parameters according to the skin type and location of lesions in one to three consecutive treatment sessions at 14-21 day intervals for three month. Two months after finishing the treatment, the effect will be evaluated base on close-up photographs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052414285N2**

Registration date: **2014-07-09, 1393/04/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-09, 1393/04/18

Registrant information

Name

Zahra Hosseininezhad

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intense Pulsed Light in Treatment of Nevus Spilus in in patients attending dermatology clinic of razi hospital

Public title

Intense Pulsed Light in treatment of Nevus Spilus in patients attending dermatology clinic of razi hospital

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : nevus Spilus confirmed via histopathology Exclusion Criteria : pregnancy; lactation; tanning, scar formation history; previous treatment with laser

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Quods Ave, Keshavarz Bulvar, Tehran, IRAN

City

Tehran

Postal code

14174

Approval date

2013-05-12, 1392/02/22

Ethics committee reference number

92/130/230/3

Health conditions studied

1

Description of health condition studied

Nevus Spilus

ICD-10 code

D22, D22.3

ICD-10 code description

Melanocytic naevi

Primary outcomes

1

Description

Decrease in Color Density

Timepoint

one months

Method of measurement

Photography Comapring

Secondary outcomes

1

Description

Ulceration

Timepoint

Beggining of the study, First Month, Second Month, Third Month, at the end of the study

Method of measurement

Clinical Exam

2

Description

Hypopigmentation

Timepoint

Beggining of the study, First Month, Second Month, Third Month, at the end of the study

Method of measurement

Clinical Exam

3

Description

Scar formation

Timepoint

Beggining of the study, First Month, Second Month, Third Month, at the end of the study

Method of measurement

Clinical Exam

Intervention groups

1

Description

Included patients will be treated by Intense pulsed light system with these parameters: pulse width 10-30ms, Fluence 44-50 jouls. treatment will be conducted for three consecutive sessions one month time window between them, after every session photography of lesions will be done.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Shirin Gojehlou

Street address

1199663911, Razi Ave, Vahdate eslami Ave, Hafiz Street, Tehran IRAN

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi Hopsital, Tehran University of Medical Sciences

Full name of responsible person
Mis. Gojehlou
Street address
Tehran, Razi Hopsital
City
Tehran
Grant name
مرکز تحقیقات بیماریهای تاولی بیمارستان رازی
Grant code / Reference number
11121
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razi Hopsital, Tehran 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
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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