

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the Effectiveness of PDL laser with or without topical sirolimus 0.2% for treatment of portwine stain

Protocol summary

Study aim

To investigate the efficacy of Pulsed Dye Laser with or without topical sirolimus for treatment of port wine stain.

Design

A concealed, randomized, double blind inter_patient placebo controlled clinical trial(phase 3) with a parallel group design of 15 patients. Block randomization has been done.

Settings and conduct

15 patient will treat in razi hospital with PDL (in whole of lesion) every 8 weeks up to 6month(4 sessions) with using sirolimus 0.2% in one part and the placebo on another part every night after laser therapy. Serum sirulimus level at the end of 2th and 6th months will be evaluate. Phothography before first PDL and 2month after last treatment will be done. Side effects of the procedure were also recorded at each session.

Participants/Inclusion and exclusion criteria

1 to 50 years old patient; no contrandiation for sirulimos; no treatment for port wine stain during previous 6 months

Intervention groups

using pdl laser with sirulimos or placebo in every part of lesion

Main outcome variables

reducing in erythem of lesion

General information

Reason for update

Acronym

PWS :Port Wine Stain

IRCT registration information

IRCT registration number: **IRCT20170617034590N2**

Registration date: **2018-09-07, 1397/06/16**

Registration timing: **retrospective**

Last update: **2018-09-07, 1397/06/16**

Update count: **0**

Registration date

2018-09-07, 1397/06/16

Registrant information

Name

Zahra Hallaji

Name of organization / entity

Razi Skin hospital

Country

Iran (Islamic Republic of)

Phone

+98 55618989

Email address

halajiza@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1- Vice-chancellor for Research of Tehran University of Medical Sciences 2- Behestan Darou (P.J.S)

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2017-12-01, 1396/09/10

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of PDL laser with or without topical sirolimus 0.2% for treatment of portwine stain

Public title

Effect of Pulsed Dye Laser and topical sirolimus for treatment of port wine stain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1 to 50 years old patient with portwine stain Not received any treatments during the last 6 months

Exclusion criteria:

Being pregnant, actively trying to become pregnant or breast-feeding previous history of malignancy Having hypersensitivity or contraindication to the treatments

Age

From **1 year** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

In every patient ,lesion will be divided to equal part and use placebo in one part and sirulimos in another.

Actual sample size reached: **15**

More than 1 sample in each individual

Actual sample size in each individual: **2**

In every patient ,lesion will be divided to equal part and use placebo in one part and sirulimos in another.

Randomization (investigator's opinion)

Randomized

Randomization description

With block randomization we use sirolimus and placebo in upper or lower parts of lesion

Blinding (investigator's opinion)

Double blinded

Blinding description

patients used labaled_cream (up and down) .

dermatologist who did laser and analyzing the pictures having no data about placebo or treatment site.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee 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

Province

Tehran

Postal code

1416634391

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

ir.tums.medicine.rec.1396.3368

Health conditions studied

1

Description of health condition studied

port-wine stain

ICD-10 code

Q82.5

ICD-10 code description

Congenital non-neoplastic naevus

Primary outcomes

1

Description

reducing erythem in lesion

Timepoint

2months after last treatment

Method of measurement

photographs taken on months 0 and 2 months after last treatment and analyze with visioface device(to determine of reducing erythma in quantity)

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

At the end of the study

Method of measurement

Patient Global Assesment (asking them to score 0 _10)

Intervention groups

1

Description

Intervention/control 1: PDL on months 0, 2, 4 and 6 in whole of lesion(control and treatment site)

Category

Treatment - Other

2

Description

Intervention 2 :using sirulimos in one part of lesion

Category

Treatment - Drugs

3

Description

Control group: using cream of placebo in one part of lesion

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Hamid-Reza Mahmoudi

Street address

Razi Skin Hospital, Razi Ave., Vahdate eslami Ave., Hafiz St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Web page address

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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 Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

2

Sponsor

Name of organization / entity

Behestan Darou (P.J.S)

Full name of responsible person

Dr. Hamid-Reza Mahmoudi

Street address

Behestan Darou (P.J.S), 5th floor, Soraya Bldg., Pardis st., Mollasadra Ave.

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Web page address

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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

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Razi Hospital
Full name of responsible person
Hamid-Reza Mahmoudi
Position
Associate Professor
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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