

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

To investigate the efficacy and safety of single pass Pulsed Dye Laser (PDL) with double pass Pulsed Dye Laser(PDL) ,within 20 minutes interval, for treatment of port wine stain(PWS)

Protocol summary

Study aim

To investigate the efficacy and safety of double pass Pulsed dye laser (PDL) with single pass PDL in treating port wine stain(PWS)

Design

A concealed, randomized, non blinded, inter_patient placebo controlled clinical trial with a parallel group design of 23 patients. Block randomization has been done.

Settings and conduct

23 patient will treat in razi hospital with pulsed dye laser (PDL) ,in whole of lesion, every 4 weeks up to 3month(3 sessions) . The port wine stain (PWS)lesion is divided in two portion (up and down) in the same dermatome .one part randomly receive long pulse PDL laser:Pulse duration 20 and frequency 13 and after 20 minutes the whole lesion will be treated with short pulse PDL laser :pulse duration 1.5 and frequency 11. Phothography (visoface) and photofinder before first PDL and 1month after last treatment will be done. Side effects of the procedure were also recorded at each session. three patient who have congenital PWS are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who have congenital port wine stain and are older than 10 years Exclusion criteria: patient who has treated PWS previously and children who can not tolerate PDL without general anesthesia

Intervention groups

Intervention group: Treatment of port wine stain (PWS) with Double pulse pulsed dye laser (PDL) , long pulse duration and short pulse duration within 20 minutes interval Control group : Treatment with short pulse PDL laser.

Main outcome variables

Degree of erythema ; side effects (Purpura; hypopigmentation; hyperpigmentation; scar)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180815040808N1**

Registration date: **2019-02-02, 1397/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-02, 1397/11/13**

Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

Zahra Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5561 8989

Email address

razavi_z@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the efficacy and safety of single pass Pulsed Dye Laser (PDL) with double pass Pulsed Dye Laser(PDL) ,within 20 minutes interval, for treatment of port wine stain(PWS)

Public title

Effect of double pass PDL in treatment of PWS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have congenital port wine stain are included in the study Patients are at least 10 years old Patients should fill the informed consent before inclusion in the study

Exclusion criteria:

Patients who have treated the port wine stain previously Children who can not tolerate laser without general anesthesia

Age

From **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

More than 1 sample in each individual

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

In every patient ,lesion will be divided to two part and use single pass in one part and double pass in another

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization

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 Tehran University of Medical Sciences

Street address

Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education

Bldg, Poursina

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR. TUMS. MEDICINE. REC.1397.249

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

Evaluation the degree of erythema of the lesion

Timepoint

Before starting the treatment and one month after the last (third) session of the laser

Method of measurement

photographs taken on months 0 and 1 month after last treatment and analyze with visioface device(to determine of reducing erythma in quantity) and photofinder (to evaluate the microscopic features of the vessels before treatment and evaluate the exact reduction in erythema quantity)

Secondary outcomes

1

Description

Laser side effects

Timepoint

Monthly

Method of measurement

According to physical exam and pictures

Intervention groups

1

Description

Intervention group 1 :Twenty three patients who have port wine stain included in the study.One part of the lesion which has been choosed randomly will recieve long pulse PDL laser with (pulse duration 20 and fluence 13) .For example, Some of the patients will recieve the

mentioned laser on the upper portion of the lesion, while others will receive on the lower portion of the lesion. Patients will receive laser in months 0,1&2.

Category

Treatment - Devices

2**Description**

Intervention group2: The same twenty three patients receive short pulse Pulsed dye laser (PDL), (pulse duration 1.5 and fluence 11), on the whole port wine stain (PWS), after 20 minutes in months 0,1&2.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi dermatology hospital

Full name of responsible person

Dr. Amir housing ehsani

Street address

Razi skin hospital, Razi Ave, Vahdate eslami Ave, Hafiz St

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Ehsanih@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali sahraeian

Street address

Qods Ave., Keshavarz Blvd.

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Razavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Scientific research

From where data/document is obtainable

Zahra Razavi

What processes are involved for a request to access data/document

The application is sent by official university email which should contain the recipient's information and the purpose of his/her request. After having verified the accuracy of the information, files would be sent.

Comments