

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of Therapeutic Effects of Pulsed Dye Laser and Pulsed Dye+CO2 Lasers on Treatment of Port Wine Stain

Protocol summary

Study aim

Comparison of therapeutic effects of Pulsed Dye Laser(PDL) and CO2 + PDL in treatment of Port Wine Stain

Design

Non randomized clinical trial with control group and blinded outcome assessment with sample size of 15 persons

Settings and conduct

This is a clinical trial on patients with port wine stain in Dr Radmanesh dermatology clinic in Ahvaz

Participants/Inclusion and exclusion criteria

Patients with port wine stain who are above 10 years old; aren't pregnant and don't lactate; negative history of hypertrophic scar and keloid and don't have active infection or acne

Intervention groups

Intervention group is inferior part of lesions which is treated with CO2 + Pulsed Dye Lasers and control group is superior part of lesions which is treated only with Pulsed Dye laser

Main outcome variables

Clearance of port wine stain lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180402039169N1**

Registration date: **2018-04-20, 1397/01/31**

Registration timing: **retrospective**

Last update: **2018-04-20, 1397/01/31**

Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

younes joonaki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Therapeutic Effects of Pulsed Dye Laser and Pulsed Dye+CO2 Lasers on Treatment of Port Wine Stain

Public title

Effect of Pulsed Dye + CO2 Lasers in treatment of Port Wine Stain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with Port Wine Stain Patients above 10 years old

Exclusion criteria:

Female patients with pregnancy and lactation Patients with history of hypertrophic scar and keloid active

infection and acne in treatment areas

Age
From **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Only the persons who measure the outcome are blinded, they don't know which part of lesions are treated with both CO2 + Pulsed Dye lasers and which part is treated only with Pulsed Dye laser

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ground floor, chancellor of Research, Ahvaz Jundishapur University of Medical Sciences, Daneshgahi town, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2018-01-23, 1396/11/03

Ethics committee reference number

IR.AJUMS.REC.1396.904

Health conditions studied

1

Description of health condition studied

Port Wine Stain

ICD-10 code

Q82.5

ICD-10 code description

Congenital non-neoplastic nevus

Primary outcomes

1

Description

Treatment of Port Wine Stain lesions according to clearance score

Timepoint

Six months after treatment

Method of measurement

Clearance score according to percent of clearance of lesions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: we treat inferior part of lesions with CO2+Pulsed Dye Lasers

Category

Treatment - Devices

2

Description

Control group: we treat superior part of lesions with only Pulsed Dye Laser

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Radmanesh dermatologic clinic

Full name of responsible person

Younes Joonaki

Street address

4th east street, Kianpars Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ground floor, vice chancellor of Research, Ahvaz
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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Younes Joonaki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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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

Not applicable

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