Modified treatment of port wine stains with the pulsed dye laser: a randomised controlled trial

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The primary objective of this study is to assess the efficacyand safety of modifications of the laser treatment to increase the clearance of port wine stains.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON30414

Source
ToetsingOnline

Brief title
Laser in port wine stain

Condition

- Skin vascular abnormalities

Synonym
capillary malformation, port wine stain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: port wine stain, pulsed dye laser, treatment

Outcome measures

Primary outcome

Clearance of the port wine stain as assessed by colour measurement through

reflectance spectroscopy by a blinded investigator.

Secondary outcome

Visual assessment of clearance and side-effects by a blinded investigator.

Study description

Background summary

Modified treatment of port wine stains with the pulsed dye laser: a randomised controlled trial

Pulsed dye laser (PDL) is the first choice for the treatment of port wine stains (PWS). However, the outcome is highly variable and there is a substantial part of patients resistant for further treatment. Especially the small capillaries in PWS are resistant to laser treatment. Increasing the dermal blood volume or a second pass may improve the outcome of laser treatment of PWS.

Study objective

The primary objective of this study is to assess the efficacy and safety of modifications of the laser treatment to increase the clearance of port wine stains.

Study design

Prospective single blinded randomised within-patient controlled study.

Intervention

Two similar parts of the PWS measuring 2x2cm will be randomly allocated to PDL

treatment with or without modification of the technique.
Modification in PWS*s on the extremities involves an increase of dermal blood volume by inflating a blood pressure cuff (90±10 mm Hg).
Modification in PWS*s in other regions involves a second pass after 6 minutes.

A long pulse PDL (V beam laser) operating at 595 nm will be used with standardised settings. Three months after two treatments, 8 weeks apart, the clearance of the PWS will be assessed using both visual assessment and objective colour measurement.

Study burden and risks

Subjects participating in the study will not experience delay in the treatment of the PWS as the whole PWS will be treated at each visit. No additional visits are necessary for the present study. The extra time investment for the patient will be 15 minutes at each of the three visits not exceeding a total of 60 minutes. Additional procedures as compared to regular therapy are colour measurements, the application of an inflated blood pressure cuff (extremities) or a second pass after 6 minutes (not extremities). As a result of the study temporary stronger purpuric skin reactions may be expected in the region (2x2 cm) treated by modified PDL. All together the burden due to the study is minimal and the expected risk is very low and confined to a region of 2x2cm. Except for a stronger purpuric colour, we do not expect a higher frequency of local side effects as compared to regular laser treatment. Systemic side effects are not associated with this kind of laser treatment. If the assessed modifications are effective, a substantial part of our patients may benefit from higher clearance rates in the treatment of PWS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Subjects with at least one PWS treated previously with the PDL 3 times or more
- PWS with two homogenously coloured parts of at least 2x2 cm;
- Subjects following laser treatment at the Netherlands Institute for Pigment Disorders;
- Age at least 18 years.

Exclusion criteria

- Subjects with hypertrophic PWS;
- Subjects with dark purple PWS;
- In case of a scar after the first PDL treatment in one of the study regions, the patient will be withdrawn from the study.
- Subjects who fail to appear at the planned follow-up visits.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	33
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL15191.018.06