A preliminary study on the effect of photothermal laser therapy on the vascularization and innervation of psoriatic lesions*

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This project aims to assess the effect of laser therapy on the blood vessels and (peripheral) innervation of psoriasis plaques. The primary objective is to quantify the regression and recovery of nerves compared to blood vessels. We hypothesize that...

Ethical review	Approved WMO
Status	Completed
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON54478

Source
ToetsingOnline

Brief title
Laser induced changes to innervation and vascularisation of psoriatic skin

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis, Psoriasis Vulgaris

Research involving
Human

Sponsors and support

Primary sponsor: ZBC Multicare B.V.

Source(s) of monetary or material Support: ZonMW,Eigen financiering vanuit de sponsor

Intervention

Keyword: Psoriasis, Pulsed dye laser, Selective photothermolysis

Outcome measures

Primary outcome

The primary study parameter is the difference in ratio between linear nerve density to linear blood vessel density between the pre-treatment, and post-treatment biopsies. This will be named the recovery ratio (nerves/blood vessels). The tested hypothesis is that laser therapy results in a decrease in nerve fibre density.

Secondary outcome

The secondary objective is to assess any relationship between the dermal architecture (in terms of blood vessels and nerves) and leukocyte infiltration before and after SPT treatment.

Study description

Background summary

Vascular laser therapy for psoriasis seems to achieve a remarkably long treatment-free duration of remission. But why would sub-second heating of the blood vessels of the skin result in a year-long resolution of an infamously stubborn condition? The only other situation in which such long term clearance is observed is in patients that experience significant damage to the innervation, such as paraplegia. Even then the duration of remission is correlated with the persistence of the injury. Fortunately laser therapy is not associated with permanent nerve damage, but it does raise the question if it is through an effect on the local innvervation that laser therapy results in a cessation of the inflammation.

Unraveling the mechanism of action of laser therapy would not only allow for

the improvement of existing laser therapy protocols but also, could open the door to a whole new range of interventions offering quasi-permanent solutions for patients. There is a high need for such enduring therapies: Psoriasis is both, a common and a costly skin condition. It affects between 1% and 9% of the population and has a very severe impact on the quality of life of the patient. It's chronic character implies lifelong treatment, and the associated risks and effort.

Study objective

This project aims to assess the effect of laser therapy on the blood vessels and (peripheral) innervation of psoriasis plaques. The primary objective is to quantify the regression and recovery of nerves compared to blood vessels. We hypothesize that the recovery of nerves after SPT is decreased compared to the recovery of blood vessels.

Study design

Randomized single blinded intra patient comparative study.

Intervention

Patients undergo regular 595 nm pulsed dye laser therapy for psoriasis. Tissue samples will be collected from the patients using a total of two 3 mm punch-biopsies under local anesthesia. These samples are used to determine the nerve density and blood vessel density in the treated and non-treated lesions.

Study burden and risks

During standard laser treatment for psoriasis, two tissue samples will be acquired using 3 mm punch biopsies. As a consequence, two small permanent scars (2x 7mm^2) are infliced upon the patients. The study is not expected to involve significant risks or benefits compared to standard dermatological treatments for psoriasis.

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

18 - 69 years of age
- Psoriasis vulgaris
- Skin type I - III
- At least two lesions with of surface area of 3 cm2
- Contralateral psoriasis vulgaris lesions located on at least one of the following locations:
* trunk
* upper arms
* upper legs

Exclusion criteria

The participant receives other treatments for psoriasis or affecting during the study or two weeks before the start of the study

The participant suffers from any known neurological, vascular, or immunological condition other than psoriasis.

The participant is allergic to lidocain

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	09-12-2022
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75576.100.20