Protocol of Placebo controlled double blind study for the treatment of psoriasis with blue light

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The target of this study is to determine if blue light of 420 nm is effective against psoriasis

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

Summary

ID

NL-OMON31457

Source
ToetsingOnline

Brief title
Tratment of Psoriasis with blue light

Condition

- Epidermal and dermal conditions

Synonym
Plaque Psoriasis, Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Philips,Philips Research

Intervention

Keyword: Blue, LED, Light, Psoriasis

Outcome measures

Primary outcome

The LPSI calculation method is used:

LPSI = erythema + scaling + induration

The sum of the scaling, erythema and plaque elevation (induration) gives rise

to the LPSI score (0 to 12). Patients with a LPSI score of the target lesion

5 at Baseline/Visit Day 1 may be included in the trial.

The patients will be visited at the:

- Screening

- Baseline (beginning of week 1)

- Beginning of week 3

- End of week 4 + 1 (working) day

At each visit possible adverse events, like pigmentation and/or erythema (in a

scale from 0 to 4) will be notified.

At Baseline, beginning of week 3 and end of week 4 +1 (working) day a picture

will be taken.

Secondary outcome

N.v.t.

Study description

Background summary

Psoriasis is a not contagious skin disorder characterized by red and scaled plaques, which can occur on the whole body. Often this disorder is hereditary. Psoriasis can be improved very much with treatment, but no therapy can cure this skin disease definitely.
Psoriasis is characterized by an accelerated cell division in the epidermis and by inflammation symptoms in the epidermis and dermis.
The precise cause is not known, but genetic predisposition is very important. In people with this predisposition different factors make psoriasis break out. Examples of these are damage of the skin, infections, use of medicines and psychological stress.
Psoriasis can start at any age. The most occurring form of psoriasis is called plaque psoriasis, being the characteristics red scaled plaques sharply delimited. The plaques vary in size and can come together forming bigger plaques with different shapes. The psoriasis plaques can appear anywhere in the body, but especially on elbows and knees, the head with hair, and the back. On the palms and soles the psoriasis can be coupled to painful cleaves.

Study objective

The target of this study is to determine if blue light of 420 nm is effective against psoriasis

Study design

Patients are included after checking the inclusion and exclusion criteria and signing an informed consent
Every Friday, Saturday and Sunday the plaques are treated with Salicylic acid 10% in petrolatum in order to remove excessive scaling and on Monday the patient will start/continue the treatment with blue light.
Previous to every light treatment the two plaques to be treated will be wetted with water.

Irradiation (at the distance of few centimeters from the plaque)
20 patients get 20 min treatment 3x week, for 4 weeks, ~90 mW/cm2 with the real device (LED*s based blue light 420 nm) on one plaque, and ~90 mW/cm2 with the placebo device (LED*s based red light 630 nm) on the other plaque.

Intervention

N.v.t.

Study burden and risks

Blue light belongs to the spectrum of visible light. Based on the wavelength and intensity used in this study the chance of side effects is limited to a possible slight and temporary erythema. Because no UV radiation is emitted, the

chance of side effects as effect of UV radiation (premature aging, skin cancer) is considered negligible

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

· Male or female patients, 18 years or older.
· Patient suffering from plaque psoriasis demonstrated through documentation in their medical history for at least 6 months.
· Current stable disease for at least 6 months as documented in medical notes
· Patient has a total psoriasis affected Body Surface Area (BSA)< 10%
· Two target lesion, symmetrically localized, with the following criteria;
o Located on the trunk or extremities (excluding the extension surface of the elbows and knees, hands, feet, groin, scalp and genital areas)

o Size of approximately 4 cm in diameter
o LPSI score> 5
· Patient agrees to comply with the study requirements and attend all required visits.
· No concomitant light treatment including sunbathing or use of commercial sun beds.
· Patients must be capable of understanding the purpose and the risk of the trial, and have given written, informed consent
· Patient meets the concomitant medication washout requirements as indicated in the protocol (pag. 4) and agrees to follow restrictions during the study

Exclusion criteria

- Patients with very severe scales (Scaling 4)
- Patient has a skin disorder other than plaque or patch psoriasis in the areas to be treated. This includes, but is not limited to, pustular psoriasis, erythrodermic psoriasis, guttate psoriasis, or a cutaneous infection
- Patient has a knows diagnosis or history of cancer or HIV
- Patient has a medical condition or disorder that, in the opinion of the investigator, precludes the patient from participating in the study
- Patient is pregnant or breast feeding an infant
- Current or participation in the previous 28 days in another clinical trial of any sort
- Patient with known, documented history of alcohol or drug abuse
- Patient with target lesions located on the head, hands, extension sites of elbows and knees, feet or genitalia.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	15-02-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL20950.091.07