# Sking hardening in polymorphic light eruption. Comparison of therapeutic effect of UVB hardening in the hospital with treatment at home with Sunshower

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In this study we will evaluate the effect of Sunshower Medical device at home and compare it with the effect of customary UV hardening performed in the hospital to assess whether the former is not inferior to the latter treatment. The ultimate goal…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Epidermal and dermal conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON35008

**Source**
ToetsingOnline

**Brief title**
UV-hardening versus Sunshower

### Condition

- Epidermal and dermal conditions

**Synonym**
polymorphic light eruption, sunallergy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Sentavi bedrijf

## Intervention

**Keyword:** polymorphic light eruption, quality of life, UV-treatment

## Outcome measures

### Primary outcome

1. Validated questionnaires related to the quality of life and the extension of

PLE.

2. Changes in the results of UV provocation tests as a result of the UV

hardening

### Secondary outcome

Satisfaction with the UV hardening therapy (questionnaire).

Evaluation of unwanted reactions of the skin caused by the UV therapy and

sunshine.

# Study description

### Background summary

Polymorphic light eruption (PLE) is one of the skin diseases caused by sunlight. Epidemiologic studies have shown that approximately 17% of people living in the Netherlands suffer from this photodermatosis. The clinical picture of PLE consists of many intensely itching macules, papules or vesicules which appear on the exposed skin. These skin changes remain present for several days or weeks and than they disappear spontaneously - if no new sun exposure is taking place. In general, PLE can affect the quality of life of the patients in a very negative way. Some of them do not dare to go outside during a sunny weather and also the choice of their summer holidays is negatively influenced by this disease.
Diagnosis of PLE can be established on the basis of patient history and clinical picture. When there are some diagnostic doubts, histological investigation can provide some help. Because patients often visit the dermatologic departments without any visible skin symptoms, the UV provocation

tests can help in the establishing diagnosis. These tests are positive in 60-90% of the patients.

Preventive therapy
In many patients, the exposure to low, slowly increasing dose of UV radiation can prevent the development of sun allergic reaction. This adaptation response of the skin (also called hardening) has become the treatment of the first choice for PLE patients. The hardening consists of a series of UV irradiations performed 2-3 times a week for several weeks. The patients have to come for this therapy to the hospital. However, it is necessary that patients take care of their regular sun exposure themselves after the hardening therapy and in this way they prolong the hardening effect. However, this is not always possible; success percentages of 70-90% have been reported for the hardeniogn therapy. A success percentage of 91% was found in an older study on 68 of our PLE patients (unpublished). The effect of hardening therapy can disappear within few weeks.

Sunshower
A Dutch company Sentavi has developed a new product for the bathroom market - Sunshower. Its variant is named Sunshower Medical. It is a UV producing apparatus placed in the shower. This UV source (class III) makes it possible to expose daily the skin to UV radiation during 5-10 min. With this apparatus the skin should have possibility to build up the adaptation. According to some recent research, the low dose of UVB radiation causes positive adaptation response of the skin cells.
The low UV intensity and the possibility to use this instrument at home makes Sunshower Medical an interesting device that could be used by PLE patients for their skin adaptation.

## Study objective

In this study we will evaluate the effect of Sunshower Medical device at home and compare it with the effect of customary UV hardening performed in the hospital to assess whether the former is not inferior to the latter treatment. The ultimate goal is to be able to prescribe the treatment at home with the Sunshower as a good alternative to the treatment in the hospital as the latter poses quite a strain on the patient because of the many hopital visits involved.

## Study design

Recruitment of the patients
The data of more than 100 patients with PLE are present in the Department of Dermatology. Only the patient with the diagnosis of PLE established by a dermatologist will be considered for this study. These patients will receive a short letter asking them whether they would be willing to participate in this

comparative study. For the patients who shall positively respond, appointment on the out-patient department will be made. At the same time they receive detailed written information about this study.
The first appointment on the out-patient department
1. The detailed information will be once more discussed with the patient and questions will be answered. The patient will sign the patient*s consent.
2. The exclusion criteria will be examined.
3. The blood will be taken for ANF test (only if this routine determination has not been performed recently)
4. The question forms will be filled in.
The patients who fulfill all the criteria will be coded and randomized for the UV hardening in the hospital or for home therapy with Sunshower device.

Group A: 20 -25 patients get UV hardening therapy in the hospital. This therapy will be performed in the Department of Dermatology LUMC and in three other Dermatology Departments, where the same UV apparatus is present. The hardening 2-times a week will be carried out according to same irradiation scheme for 6 weeks.
Group B: 15-20 patients will be treated at home with Sunshower Medical device. This apparatus will be placed in their showers free of charge. At the same time, each patient will receive instructions how to use the apparatus and the treatment scheme.
All patients also receive record lists where they shall note down development of unwanted skin reaction causes by the UV irradiation or by the sun.
Provocation tests.
Before the start of skin hardening all patients will undergo UV provocation tests. In order to reduce the variation of the results, all the provocation tests will be performed in one hospital only (LUMC).
The first check up.
The first control will take place six week after the start of hardening therapy. All patients will be monitored in the LUMC. Each patient will be asked to fill in two questionnaires. In addition, the UV provocation test will be performed. The patients using home therapy will continue using this therapy. All patients will be asked to go on with filling in the record lists concerning unwanted skin reactions.
The second check up.
The second (last) control will take place in the LUMC two months later. Each patient will be asked to hand over the record list and to fill in the questionnaires.

**Intervention**

The intervention is profilactic treatment of patients with Polymorphic Light Eruption by a photo-hardening therapy.
Group A of patients, the controle group, receive this treament in the hospital, whereas group B apply such a treatment to themselves at home while

showering by using the Sunshower device.

**Study burden and risks**

There are no unexpected risks for the patients.
Some patients with a very sensitive skin may develop a skin reaction during the UV hardening in the hospital. In the most cases, the dose of UV will not be increased the next day, or it can be lowered. The patients using Sunshower device at home receive written information how to deal with these skin reactions at home.
The time burden for the patients consists only of additional visits of the hospital connected with the UV provocation tests.

# 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

proven polymorphic light eruption
age 18-70 years

### Exclusion criteria

positive ANF test
sun holiday less than 3 months before
use of immunosuppresives
skin cancer in the patient's history
prognancy (because of risk of melasma)

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-02-2010 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 08-02-2010 |

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| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# 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 | NL30790.058.09 |