# Longterm carcinogenic effects of daily low emission phototherapy in psoriasis

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To ascertain the amount of UV-damage (p53 activation, apoptosis, thymidine dimers and γH2AX) is caused by the Dermasun treatment in psoriasis patients.Total skin check in patients using Dermasun for a prolonged period of time to screen for...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Skin neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON48614

**Source**
ToetsingOnline

**Brief title**
UVTOX

### Condition

- Skin neoplasms malignant and unspecified

**Synonym**
psoriasis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Dermasun Medical B.V.,sponsoring

## Intervention

**Keyword:** carcinogenic effects, daily, phototherapy, psoriasis

## Outcome measures

### Primary outcome

To ascertain the amount of UV-damage (p53 activation, thymidine dimers,

apoptosis and γH2AX) is caused by the Dermasun treatment in psoriasis patients

in comparison to conventional smallspectrum UV-treatment and no UV treatment.

### Secondary outcome

Number of (pre-) cancerous skin lesions found at the biopsy time point

Reported actual use of Dermasun by patients after having Dermasun in their

homes for at least a year.

# Study description

### Background summary

Several forms of phototherapy are available to psoriasis patients: narrowband UVB thrice weekly is the standard treatment. Recently we performed a study to assess the effectivity of a daily low emission phototherapy device (DermaSun Medical). Preliminary findings during the first few months of treatment showed no carcinogenic effects.
This treatment modality is used at home, and patients can use this device at their own volition.

Since, this device has been used in a larger number of patients (over 200) for several consecutive years. To ascertain the long term effects of treatment with this home based device an additional study is needed.

### Study objective

To ascertain the amount of UV-damage (p53 activation, apoptosis, thymidine dimers and γH2AX) is caused by the Dermasun treatment in psoriasis patients.

Total skin check in patients using Dermasun for a prolonged period of time to screen for (pre-) cancerous skin lesions
Check what actual usage of the Dermasun retrospectively is in patients when it is readily available to patients on a daily basis

**Study design**

The study is an observational cross-sectional cohort study. Three cohorts of psoriasis patients will be analysed:

• using Dermasun treatment for a prolonged period of time;

• undergoing conventional narrowband UVB treatment

• not undergoing UV-treatment (yet)

The study has one timepoint where measurement will be performed.

The analysis of the actual use of the Dermasun in patients in cohort is a retrospective study part.

**Study burden and risks**

Patients will be asked to perform one out-patient visit to the dermatology clinic. Two 4 mm skin biopsies will be taken, preferably from the buttocks region. Skin biopsies usually heal without scarring.

# 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 years old
psoriasis;Depending on the research arm:
- undergoing conventional phototherapy for at least 4 weken
- undergoing low emission phototherapy for at least 18 maanden
- not undergoing phototherapy or any systemic treatment for psoriasis

## Exclusion criteria

systemic medication for treatment of psoriasis
unable to give informed consent

# Study design

## Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-05-2019 |
| Enrollment: | 110 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 08-03-2019 |
| 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 | NL66853.029.18 |