

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 Derasun treatment in psoriasis patients.Total skin check in patients using Derasun for a prolonged period of time to screen for...

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: Derasun 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 γ H2AX) is caused by the Dermasun treatment in psoriasis patients in comparison to conventional small spectrum 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 γ H2AX) is caused by the Dermasun treatment in psoriasis patients.

Total skin check in patients using Derasun for a prolonged period of time to screen for (pre-) cancerous skin lesions
Check what actual usage of the Derasun 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 Derasun 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 Derasun 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

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