Psoriasis and daily low emission phototherapy; effects on disease and vitamin D level

Published: 06-10-2011
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Assessing the value of SunshowerMedical Helios as a at home maintenance treatment for patients with psoriasis vulgaris.

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

Summary

ID

NL-OMON38060

Source
ToetsingOnline

Brief title
Psoriasis and SunshowerMedical

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Leverancier Sunshower Medical,SunshowerMedical BV

Intervention

Keyword: phototherapy, psoriasis, treatment, vitamin D

Outcome measures

Primary outcome

PASI-, Skindex-29 and DLQI-scores and their differences between groups.

Secondary outcome

Secondary study parameters:

Difference between control group and patients undergoing the home UV-treatment

in:

- serum levels of 25(OH)D3

- presence of pyrimidine dimers and/or p53-expression in epidermal cells of

patients

- amount of mometason ointment used

- parameters for metabolic syndrome (HbA1c, blood pressure)

Study description

Background summary

Psoriasis vulgaris is a common, cosmetically debilitating disease of the skin.
It is associated with arthritis and recently has been linked to higher risk for developing metabolic syndrome. Patients are treated in different manners, i.e. local corticosteroids, systemic immunosuppressants and phototherapy. This last therapy is usually given during relapses as higher dose of UV is given to patients. The effect of low dose continual UV-therapy is however not yet elucidated. With the introduction of SunshowerMedical Helios on the Dutch market, daily low dose, home phototherapy has become an practical and realistic option.
As vitamin D is stimulated by UV exposure and this vitamin is possibly also linked to metabolic syndrome, monitoring the parameters for metabolic syndrome

might prove interesting.

Study objective

Assessing the value of SunshowerMedical Helios as a at home maintenance treatment for patients with psoriasis vulgaris.

Study design

open, controlled (randomised) intervention study

Intervention

Psoriasis patients will be randomised in a control group or for daily use of a home UV-device, the Sunshower medical. Patients will be monitored in their PASI-score, quality of life, vitamin D status, blood pressure and UV damage caused by this device.

A group of 7 patients undergoing conventional TL01 UVB light therapy (group C) will also be asked permission to retrieve two skin biopsies to assess the amount of `normal` DNA damage caused by conventional UV-therapy. These patients will not participate in other aspects of the study and no extra out-patient clinic visits will be needed.

Study burden and risks

Patient visits: 3 after informed consent
Questionnaires: 3x 2 questionnaires (total 40 questions)
Physical examinations : 4x (skin only), 2x weight assessment, 2x blood pressure
Venapunction: 3x 1 blood sample for half of included patients
Skin biopsy 3mm: 2x for 12.5% of patients, usually heals without scarring + 7 patients (group C) undergoing conventional phototherapy (higher dose) and in no other way will be asked to participate in this study.

The risk associated with participation is negligible as the amount of UV that is used in this study is significantly lower than daily, maximum advised dose. It is already good clinical practice to treat (psoriasis) patient with UV-devices with a much higher dose.
For the patients in group C, a minimal risk of scarring is associated with skin biopsies.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Psoriasis vulgaris diagnosed by a dermatologist
* 18 years or above
* Informed consent
* Patients successfully treated with phototherapy (UVB/TL01) OR after successful local therapy and a history of good clearance after UV/exposure.

Exclusion criteria

* Use of fumaric acid or immunosuppressants now or in the 2 months previous to inclusion.
* Active psoriatic arthritis
* History of skin cancer
* Concurrent photosensitive skin disorders
* Planned sunny holidays during the trial
* Use of tanning booths (at home or tanning studio)
* Use of vitamine D supplement

* Pregnancy or actively planning to get pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2011
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	SunshowerMedical
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	06-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	10-12-2012
Application type:	Amendment
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	NL37130.029.11