European multi centre trial to compare the effectiveness of two different phototherapy narrow band UVB protocols in vitiligo

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Ethical review	Approved WMO
Status	Pending
Health condition type	Pigmentation disorders
Study type	Interventional

Summary

ID

NL-OMON32305

Source
ToetsingOnline

Brief title
MCT nb UVB

Condition

- Pigmentation disorders

Synonym
vitiligo, white spot disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MCT, nb UVB, phototherapy, vitiligo

Outcome measures

Primary outcome

Colour measurement by visual assessment and reflectance spectroscopy, patient*s

satisfaction and visual assessment of side effects.

Secondary outcome

not applicable

Study description

Background summary

Narrow band ultraviolet B (nb UVB) phototherapy is the first choice for the treatment of active vitiligo (newly developed depigmented macules in the last 3 months). Phototherapy requires quite long periods (6 months * 1 year) before repigmentation of vitiligo takes place. Side effect of phototherapeutic treatment is represented by the cumulative long term effects of ultraviolet rays: premature ageing of the skin (wrinkles, spots etc.) and the appearance of skin cancer/neoplasia. Our aim is to get the best results from phototherapy whilst limiting its length.

Study objective

The primary objective of this study is to compare the effectiveness of two different phototherapy protocols (continuous treatment for 6 months, or 2 continuous treatments for 2 months separated by one month interruption (2-1-2-1), with a total length of 6 months as well). Our aim is to verify whether interrupting a cycle of phototherapy is useful or not. This interruption might make the ultraviolet rays* stimulus on cells producing melanin more effective, and may also reduce the long term damage caused by ultraviolet rays.

Study design

Prospective single blinded randomised controlled multi centre study.

Intervention

nb UVB phototherapy

Study burden and risks

Subjects participating in the study will be asked to visit the SNIP 5 times. The time investment will be 15 minutes per visit. No invasive procedures will be performed. The objective colour measurement involves a handheld device producing a harmless flash of light. Known side effects of the nb UVB phototherapy are redness, pruritus, xerosis cutis, burning sensation and conjunctivitis
All together the burden due to the study is moderately low and the risk for local side effects is low. Systemic side effects are not associated with the involved treatment.

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

Active vitiligo (newly developed depigmented macules in the last 3 months)
Subjects attending the outpatient department of the SNIP;
Aged between 18-60 years;
Subject is willing and able to give written informed consent.

Exclusion criteria

Subjects not competent to understand what is involved.
Skin photo type I
Previous treatment with any kind of phototherapy in the last 6 months
Acral vitiligo (only hands and feet are affected)
Lesion(s) suspicious for malignancy
Pregnancy
High exposure to sunlight (vacation in southern countries) or UV light (UVA or UVB)

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO 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	NL21475.018.08