The effect of UVB irradiation compared with oral vitamin D supplementation on well-being in psycho-geriatric nursing home residents in the Netherlands

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Comparing the additional effects of UVB irradiation to oral vitamin D supplementation on well-being and quality of life in psycho-geriatric nursing home residents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43379

Source
ToetsingOnline

Brief title
UVB and well-being in nursing home residents

Condition

- Other condition
- Vitamin related disorders

Synonym
quality of life, vitamin D defficiency

Health condition

kwaliteit van leven

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,fonds Topaz

Intervention

Keyword: nursing home residents, UVB, vitamin D, well-being

Outcome measures

Primary outcome

Well-being and quality of life will be measured by 2 scales: the CMAI (Cohen - Mansfield Agitation Inventory) and the Cornell scale for depression in dementia and will be taken at T0,1,2 (at 0,2 and 6 months)

Secondary outcome

Vitamin D status:25(OH)D serum levels will be taken at T0,1,2 (at 0,2 and 6 months)

Other biochemical parameters of calcium homeostasis: serum levels of calcium, alkaline phosphatase, phosphate and parathyroid hormone (PTH) will be taken at T0 and T2

Study description

Background summary

Vitamin D deficiency [25-hydroxyvitamin D (25(OH)D) < 25 nmol/l] and vitamin D insufficiency [25(OH)D) < 50nmol/l] is common in older people, in particular in nursing home residents. Vitamin D deficiency causes secondary hyperparathyroidism, which leads to cortical bone loss. It may also lead to fatigue, muscle weakness and falls. Vitamin D deficiency thus contributes to the pathogenesis of osteoporosis and fractures.
Vitamin D receptors, however can be found in many other tissues and vitamin D

deficiency is associated with multiple other health problems such as increased risk of common cancer, autoimmune and cardiovascular diseases, cognitive impairment and depression. In older people, vitamin D supplementation by UVB irradiation may be preferable to oral supplementation: it can not cause toxic levels, it is cheap and easy and it helps in preventing polypharmacy. Moreover there are indications that UVB exposure has beneficial effects on health and well-being by other mechanisms than the vitamin D -pathway alone. In a pilot, prior to this study, it was shown that the older skin is very well capable of producing vitamin D: in this study weekly frontal half body irradiation with UVB, at 0,5 MED (minimal erythema dose), during 8 weeks, led to an important increase in serum vitamin D levels.

Study objective

Comparing the additional effects of UVB irradiation to oral vitamin D supplementation on well-being and quality of life in psycho-geriatric nursing home residents.

Study design

Randomized trial on the effect of UVB irradiation compared with oral vitamin D supplementation on well-being, quality of life and vitamin D serum levels in psychogeriatric nursing home residents in the Netherlands.

Intervention

Oral vitamin D supplementation (5600 IU/week) or UVB irradiation 2x/week (1,0 SED (standard erythema dose)=1 CIE dose (Comite International de l'Eclairage) of 100 J/m² which is comparable with 50 % of the MED (minimal erythema dose) of a person with skin type II (pale skin, blond hair, light eyes). For practical reasons, in all participants the (safe) time of UVB irradiation will be the same.
Participants get de UVB irradiation while they lie on their bed with their eyes protected. A Hapro ® sunbed is used which is placed at a fixed distance above the bed. Before use sunbeds will be tested, measured and inspected by the Department of dermatology of the Leiden University Medical Center.
Well-being and quality of life will be measured by 2 scales: the CMAI (Cohen - Mansfield Agitation Inventory) and the Cornell scale for depression in dementia.
The severity of dementia will be determined with the BANS-S (Bedford Alzheimer Nursing Severity Scale)

Study burden and risks

none

Contacts

Public
Leids Universitair Medisch Centrum

Hippocratespad 21
Leiden 2333 ZD
NL
Scientific
Leids Universitair Medisch Centrum

Hippocratespad 21
Leiden 2333 ZD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

nursing home residents, 70 years or above

Exclusion criteria

-contraindications against ultraviolet irradiation: actinic damaged skin including skin cancer, sun allergy, porphyria
-contraindications to treatment with vitamin D: hypercalciaemie and sarcoidosis
-the use of food supplementation with vitamin D
-known agitation, aggression or resistance to physical contact (blood tests)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2016
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	sunbed
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-04-2016
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	NL55586.058.15