

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26520

Source

Nationaal Trial Register

Brief title

VDUVB study

Health condition

Vitamin D, UVB irradiation, dementia, well-being, nursing home, long-term care

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: • WoonZorgcentra Haaglanden (WZH), den Haag

• VDL Hapro, Kapelle

Intervention

Outcome measures

Primary outcome

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Well-being, monitored with the CMAI (Cohen-Mansfield Agitation Inventory) and the Cornell scale for depression in dementia at 0, 3 and 6 months.

Secondary outcome

- Vitamin D status
- Calcium homeostasis

Study description

Background summary

Background: in older people, vitamin D supplementation by UVB irradiation may be preferable to oral supplementation: it cannot cause toxic levels; it is cheap and easy to apply and it helps in preventing polypharmacy. Moreover, there are indications that UVB exposure has additional beneficial effects on health and well-being by other mechanisms than the vitamin D-pathway alone. UVB irradiation has shown to be effective in increasing 25(OH)D serum levels in nursing home residents.

Objective: comparing the additional effects of UVB irradiation to oral vitamin D-supplementation on well-being in psycho-geriatric nursing home residents.

Method: A randomized controlled trial. Subjects are psycho-geriatric nursing home residents (N=80) admitted in two Dutch nursing homes. The intervention consists of half-body UVB irradiation, two times a week, over 6 months, with 0.5 minimal erythema dose (MED), compared to oral supplementation with 5600 IE cholecalciferol once a week. Main outcome measure is Well-being, monitored by asking the nursing staff to complete the CMAI (Cohen-Mansfield Agitation Inventory) and the Cornell scale for depression in dementia at 0, 3 and 6 months.

Study objective

UVB irradiation has an additional effect on well-being compared to oral vitamin D-supplementation in psycho-geriatric nursing home residents.

Study design

baseline (0 months), 3 and 6 months

Intervention

The intervention consists of half-body UVB irradiation, two times a week, over 6 months, with 0.5 minimal erythral dose (MED), compared to oral supplementation with 5600 IE cholecalciferol once a week.

Contacts

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Eligibility criteria

Inclusion criteria

- > 70 years of age

Exclusion criteria

- contraindications against ultraviolet radiation: actinic damaged skin including, skin cancer, sun allergy, porphyrias, use of drugs that can induce photodermatoses.
- contraindications to treatment with vitamin D3 such as hypercalcemia and sarcoidosis
- the use of vitamin D fortified supplementary feeding

- in the context of the underlying dementia, frequent anxiety or fear or aggression and known resistance to physical contact (e.g. blood tests)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion	
Date:	23-05-2016
Application type:	First submission

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
NTR-new	NL5704
NTR-old	NTR5857
Other	: P16.010

Study results