The UPDATE trial (Uvb Phototherapy in Dermatology for ATopic Eczema): A multicenter randomized controlled trial of narrowband UVB versus optimized topical therapy in patients with atopic eczema.

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Comparing the effectiveness and cost-effectiveness of narrowband ultraviolet B with optimal topical therapy (NB-UVB+OTT) versus OTT at 3 months in adult patients with atopic eczema (AE).

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

Summary

ID

NL-OMON55900

Source
ToetsingOnline

Brief title
UPDATE trial

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis, atopic eczema

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: atopic eczema, NB-UVB, phototherapy, topical therapy

Outcome measures

Primary outcome

Primary outcome measure: % patients with EASI50 (Eczema Area and Severity Index) at 3 month follow-up.

Secondary outcome

Secondary outcome measures: Delta EASI, physician-reported clinical signs, patient-reported symptoms, quality of life, long-term control, cost-effectiveness and side effects at 1-3-6-9-12 months. Quantity and potency topical steroid usage, time to starting systemic therapy and patient satisfaction with received treatment. % patients reaching Treatment Target[1] goals and % drop-outs with reasons at 3-6-9-12 months.

Study description

Background summary

Atopic eczema (AE) is a chronic fluctuating dermatological disease characterized by a pruritic inflammation of the skin. The condition poses a high global (financial) burden. One of the therapeutic options of AE is phototherapy, with narrowband UVB (NB-UVB) being the most common. The evidence of the (cost-)effectiveness of NB-UVB, however, is scarce and of low quality.

Study objective

Comparing the effectiveness and cost-effectiveness of narrowband ultraviolet B with optimal topical therapy (NB-UVB+OTT) versus OTT at 3 months in adult patients with atopic eczema (AE).

Study design

A pragmatic multicenter single blinded randomized controlled trial (RCT).

Intervention

A NB-UVB course (home or outpatient) for at least 8 and up to 16 weeks, combined with OTT for at least 3 months, versus OTT alone

Study burden and risks

Visits will occur at baseline and 1-3-6-9-12 months after start. At baseline, patient information is collected including an evaluation of medical history and a physical examination to assess Fitzpatrick skin type and physician-reported clinical signs. During each visit patients are asked to fill out questionnaires. All patients will use daily OTT for at least 3 months. Patients in the NB-UVB+OTT group undergo outpatient or at-home phototherapy 3 times a week for 8 to 16 weeks. Risks are expected to be as in daily practice.

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

- Adult (>=18 years of age) patient meeting the UK working party criteria for atopic eczema;
- AE insufficiently controlled by standard topical care and therefore eligible for NB-UVB or OTT;
- Investigator Global Assessment (IGA, 0-4) of >= 2 (moderate disease);
- Eczema Area and Severity Index (EASI) of >= 7 (moderate disease);
- Understood and voluntarily signed and dated an informed consent form prior to any study-related procedure or has a legal representative who has, and is willing to comply with the study*s requirements.

Exclusion criteria

- Contra-indication for NB-UVB;
o Genetic defects associated with photosensitivity or skin cancer;
o Heavily photo-damaged skin;
o History of multiple (>1) skin malignancies;
o Use of systemic immunosuppressants/immunomodulators;
o Use of medication associated with photosensitivity;
- Patient is already on systemic AE therapy;
- Patient is already on OTT in the past 2 months;
- NB-UVB or any systemic therapy in the past 9 months.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-02-2023
Enrollment:	316
Type:	Actual

Medical products/devices used

Generic name:	NB-UVB phototherapy cabins;panels and lamps
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-12-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2023
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	NL81882.018.22