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The efficacy and safety of a medical device sunscreen for the prevention and reduction of skin damage caused by excessive sun exposure

Submission date
10/08/2024

Recruitment status
No longer recruiting

Registration date
16/09/2024

Overall study status
Completed

Last Edited
20/05/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
3SKIN is developing a new sunscreen to help with the prevention and reduction of actinic keratosis (AK) (precancerous manifestations of the skin) in patients prone to such conditions. The primary study objective is to assess the effectiveness of 3SKIN Sunscreen in reducing the progression of AK when exposed over 3 months (± 2 weeks) to patients with sun-damaged skin with AK.
Secondary objectives are to measure the effectiveness, safety and tolerability by comparing 3SKIN Sunscreen against placebo (sunscreen alone) in patients with AK and a control group of healthy volunteers.

Who can participate?
Patients aged 18-75 years with actinic keratosis and healthy volunteers

What does the study involve?
The study involves a medical device sunscreen to be tested over 3 months. All patients will have an initial assessment of skin parameters using devices such as ultrasound, cutometer, standardised imaging and clinical assessment. The same assessment is done at the end of the study. The patient will also log compliance in an e-diary and their opinions on the ease of use and skin parameters.

What are the possible benefits and risks of participating?
Benefits: Prevention and reduction of actinic keratosis, prevention of non-melanoma skin cancers, increase in skin quality parameters.
Risks: Skin irritation, phototoxicity, contact allergy and other skin conditions that can be related to using sunscreen or other skin products for a prolonged time.

Where is the study run from?
3SKIN AS (Norway)

When is the study starting and how long is it expected to run for?
August 2023 to December 2025

Who is funding the study?
3SKIN AS (Norway)

Who is the main contact?
Oscar Solér, contact@3skin.no

Contact information

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Public, Scientific

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Additional identifiers

Protocol serial number
SMR-3839

Study information

Scientific Title
A double-blind, randomised and placebo-controlled clinical trial of the safety and efficacy of 3SKIN Sunscreen (SPF50+ with 5-ALA and Vit D3) to reduce the severity and prevent the progression of actinic keratosis in patients with sun-damaged skin, and in healthy subjects

Study objectives
To test the safety and efficacy of the prevention and reduction of actinic keratosis and cosmetic outcomes of 3SKIN sunscreen against a placebo in a double-blinded randomised controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/08/2024, Regional Committees for Medical and Health Research Ethics (Postboks 1130, Blindern, Oslo, 0318, Norway; +47 (0)228455 11; rek-sorost@medisin.uio.no), ref: 756937

Primary study design
Interventional

Study design
Single-center interventional double-blinded randomized controlled trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Prevention and reduction of actinic keratosis in patients with epidermal skin damage and increase in skin quality

Interventions
The patient is given a randomised number by Viedoc. After all assessments have been done, the patient is given instructions on how to use the device and will leave with the corresponding device as to their given randomisation number (3SKIN Sunscreen or placebo [sunscreen alone]). The patient will use the device for at least 30 minutes every day in daylight exposure and will record this in their e-diary. The duration is 3+- 2 weeks. After they will come for a follow-up visit. The device is easily administered by pressing the device and mixing the two components in the palm of their hand. If exposed to light, it should be re-applied every 2 hours. The device should be applied 15 minutes before sun exposure, up to 16 g per day. 1 dose = 1 g. All patients will receive instructions at the clinical site and in written form before leaving the clinical site.

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
3SKIN sunscreen

Primary outcome(s)
All measured at the start and end of the study/Visit 1 and Visit 2:
1. Actinic keratosis (AK) severity clinically assessed, as per Olsen grading system: 0-3, at baseline and after 3 months +-2 weeks
2. AK severity measured using the modified actinic keratosis and severity index (mAKASI) score (0-10.8) at baseline and after 3 months +-2 weeks

3. Total (AK) lesion count (TLC) clinically measured at baseline and after 3 months +-2 weeks
4. Dermatoscopic grade of AK, as per Zalaudek (2014), measured at baseline and after 3 months +-2 weeks

Key secondary outcome(s)
Efficacy measurements:
1. Intensity, low echogenic band and skin thickness measured using Dermalab Combo by Cortex ultrasound device at baseline and after 3 months +-2 weeks
2. Elasticity of the skin, retraction time, viscoelasticity and Youngs Modulus measured using Dermalab Combo by Cortex cutometer at baseline and after 3 months +-2 weeks
3. Cosmetic outcome assessed by Investigator using the Fitzpatrick wrinkle scale (FWS) at baseline and after 3 months +-2 weeks
4. Quality of life in relation to the patient's skin measured using the Dermatology Life Quality Index (DLQI) questionnaire at baseline and after 3 months +-2 weeks
5. Cosmetic outcome reported by subject using questionnaire after 3 months +-2 weeks
6. Overall treatment satisfaction reported by the subject after 3 months +-2 weeks

Safety measurements:
7. Adverse events (including adverse events of special interest, such as pain, burning, stinging, prickling sensations, erythema, itching) recorded by the patient during the study (3 months +-2 weeks)
8. Local skin reaction score (assessed by the investigator) - components: erythema, flaking /scaling, crusting, swelling, vesiculation/pustulation, erosions
(ulcerations) grades: 0 = absent, 1 = mild, 2 = moderate, 3 = severe - measured at baseline and after 3 months +-2 weeks
9. Tolerability reported by subject using a verbal rating scale (VRS), categories 0-10 for pain, burning, stinging, prickling sensations, erythema and itching - recorded during the study (3 months +-2 weeks)

Completion date
20/12/2024

Eligibility

Key inclusion criteria
Patients:
1. Clinical (visual inspection and palpation) diagnosis of sun-damaged skin of the face with clinically typical, visible, and distinct facial AK lesion(s); Olsen global lesion scale grade 1-2
2. In the judgement of the Investigator are in good general health based on medical history
3. Both genders; males and females
4. Aged 18-75 years

Healthy volunteers:
1. Both genders; males and females
2. Aged 18-75 years

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Current, active skin cancer on the face; melanoma or non-melanoma (e.g. basal cell carcinoma (BCC), squamous cell carcinoma (SCC), Bowen's disease)
2. History of photosensitivity
3. Known hypersensitivity or allergy to any of the substances under study
4. Porphyria
5. Use of any photosensitising drugs
6. Immunocompromised or immunosuppressed subjects for any idiopathic, disease-specific or therapeutic reasons
7. Use of any systemic or topical immunosuppressive treatment (e.g. corticosteroids, systemic retinoids, chemotherapy)
8. Any topical treatment of sun-damaged skin or AK on the face (incl. medication, cryotherapy, curettage, photodynamic therapy, UV therapy, excision surgery, chemical peeling (e.g. retinol or other acids) in the 28 days prior to randomisation
9. Open wounds on the face
10. Concurrent use of any vitamin D3 supplement during the trial
11. Participation in any trial with an investigational device or drug in the last 28 days (or 5x half-life of an investigational medicinal product; whichever is the longest) prior to randomisation
12. Known pregnancy or nursing mothers
13. Any clinically unstable medical conditions (e.g. recent diagnosis of a concomitant disease), at the discretion of the Investigator
14. Expected poor protocol compliance or any mental or psychiatric co-morbidities that may interfere with the study procedures or assessments in the opinion of the Investigator
15. Prior participation in this study

Date of first enrolment
11/08/2024

Date of final enrolment
17/09/2024

Locations

Countries of recruitment
Norway

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Sponsor information

Organisation
3SKIN AS

Funder(s)

Funder type
Industry

Funder Name
3SKIN AS

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	06/08/2024	20/05/2026	No	No