

Study of oral retinol, with or without medical sun protection, in patients with actinic keratosis

Submission date 13/05/2026	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/05/2026	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/05/2026	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

Efficacy and safety of oral retinol, alone or combined with medical photoprotection, in patients with actinic keratosis: a randomized, controlled, prospective, multicentric study

Study objectives

The aim of this study was to evaluate the efficacy and tolerability of oral vitamin A, administered alone (the "In" strategy) or in combination with medical photoprotection (a film-forming medical device containing SPF 50+ sunscreen and piroxicam 0.8%, the "In & Out" strategy), in modulating

the progression of actinic damage in subjects with mild-to-moderate actinic keratosis, compared with a control group.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/01/2023, Medizioni (Via Monte delle Gioie, Roma, 00199, Italy; +39 (0)631050390; medizioni@medizioni.it), ref: DC 01-2023

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Prevention

Study type(s)

Health condition(s) or problem(s) studied

Actinic keratosis (AK)

Interventions

Participants were randomized into three groups using a computer-generated allocation sequence. The patients were allocated across three treatment groups in a 1:1:1 ratio. Group A received oral vitamin A (50,000 IU daily for 6 consecutive months), in addition to standardized sun-protection recommendations. These included limiting sun exposure, avoiding direct sunlight between 10:00 and 14:00, wearing protective clothing and wide-brimmed hats, avoiding tanning devices, and applying sunscreen with SPF ≥ 30 daily. Group B received oral vitamin A at the same dosage in combination with medical photoprotection, consisting of a film-forming medical device containing SPF 50+ sunscreen and piroxicam 0.8%, applied twice daily to the face and scalp for 6 months. Group C (control group) received only standardized sun-protection recommendations.

Intervention Type

Mixed

Primary outcome(s)

1. Treatment efficacy measured using the Actinic Keratosis and Severity Index at baseline, month 3 (T3), month 6 (T6, end of the treatment), month 9 (T9, follow-up)

Key secondary outcome(s)

1. Global clinical efficacy measured using using a five-point scale ranging from “very good” to “very poor,” based on overall changes in AK lesions, at baseline, month 3 (T3), month 6 (T6, end of the treatment), month 9 (T9, follow-up)
2. Global lesion clearance measured using a similar five-point scale, specifically focused on lesion resolution at baseline, month 3 (T3), month 6 (T6, end of the treatment), month 9 (T9, follow-up)
3. Treatment tolerability measured using a four-point scale, where 0 indicated excellent tolerability (no symptoms) and 3 indicated poor tolerability (severe pain, itching, or burning), at baseline, month 3 (T3), month 6 (T6, end of the treatment), month 9 (T9, follow-up)
4. Safety measured using systematic documentation of all adverse events at baseline, month 3 (T3), month 6 (T6, end of the treatment), month 9 (T9, follow-up)
5. In a predefined subgroup of 13 patients from Groups A and B: non-invasive imaging analysis including epidermal and dermal thickness, stratum corneum thickness, and evaluation of keratinocyte atypia, graded as mild, moderate, or severe, measured using line-field confocal optical coherence tomography (LC-OCT) at month 3

Completion date

15/04/2026

Eligibility

Key inclusion criteria

Adults aged 18 to 80 years with up to six clinically diagnosed AK lesions

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

Total final enrolment

117

Key exclusion criteria

1. Presence of more than six AK lesions
2. Use of nicotinamide within 6 months prior to enrollment
3. History of skin cancer

- 4. Organ transplantation
- 5. Pregnancy or lactation

Date of first enrolment

01/04/2023

Date of final enrolment

13/05/2025

Locations

Countries of recruitment

Italy

Sponsor information

Organisation

Cantabria Labs Difacooper

Funder(s)

Funder type

Funder Name

Cantabria Labs Difacooper

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available