ISRCTN11929806 https://doi.org/10.1186/ISRCTN11929806

A study to evaluate Adex Gel in the treatment of actinic keratosis

Submission date
19/06/2026

Recruitment status
Not yet recruiting

Registration date
22/06/2026

Overall study status
Ongoing

Last Edited
22/06/2026

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
The study aims to improve understanding of how well Adex Gel works in treating actinic keratosis (AK), a common skin condition caused by long-term sun exposure. Around 65 adults aged 18 years or older will take part through GP practices in England. Researchers will assess changes in the participants skin condition over a period of 12 weeks, using a validated scoring system call the Actinic Keratosis Area and Severity Index (AKASI).

Who can participate?
Patients aged 18 years and older diagnosed with AK.

What does the study involve?
Participants will be asked to apply the study product, Adex Gel, three times daily. The study involves 4 visits to a GP Centre over a 12-week period, where the doctor will assess the participants skin condition and the participant will be asked to complete some questionnaires on their skin condition and opinion of Adex Gel. The participant will also complete a Diary throughout the study duration to record all applications of Adex Gel.

What are the possible benefits and risks of participating?
Participants may benefit from receiving a treatment that improve their skin condition. The study may also help improve care for future patients with actinic keratosis. As the treatment is already approved , the risks are those normally linked with this product. These may include localised skin reactions upon application, such as redness, irritation, or tingling.

Where is the study run from?
The study is being carried out in NHS GP practices across England.

When is the study starting and how long is it expected to run for?
June 2026 to March 2027.

Who is funding the study?
Dermal Laboratories, UK.

Who is the main contact?
Miss Erika Houston, deni04@o4research.com

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Simon Royal

Contact details
University of Nottingham Health Service
Cripps Health Centre,
University Park
Nottingham
United Kingdom
NG7 2QW
+44 0115 822 7979
simon.royal@nhs.net

Type(s)
Public

Contact name
Miss Erika Houston

Contact details
O4 Research Ltd, Innovation Centre, Queen’s Road, Titanic Quarter
Belfast
United Kingdom
BT3 9DT
+028 9024 4764
deni04@o4research.com

Additional identifiers

Integrated Research Application System (IRAS)
371545

Central Portfolio Management System (CPMS)
74092

Protocol number
DENI-04

Study information

Scientific Title

DENI-04: A PMCF study to evaluate the clinical performance and safety of Adex Gel at 12 weeks in patients with dry and inflamed skin presenting with actinic keratosis (AK)

Acronym
DENI-04

Study objectives
This is a post market clinical follow-up study of an already marketed CE-marked medical device (Adex Gel) used within its certified marketing authorisation. The aim is to better understand how well Adex Gel works in treating the dry and inflamed skin associated with AK.

The primary objective is to evaluate the performance of Adex Gel in the treatment of AK at 12 weeks as measured by AKASI.

Secondary Objectives:
• To evaluate the short-term performance of Adex Gel in the treatment of AK at 4 and 8 weeks as measured by AKASI
• To assess the change in the number and severity of AK lesions present on the head, ears and scalp at 4, 8 and 12 weeks
• To evaluate investigators' overall assessment of treatment performance and satisfaction with outcomes
• To assess the change in AK symptoms from baseline to Week 12
• To evaluate participants' overall assessment of treatment performance and satisfaction
• To evaluate participants' treatment compliance with Adex Gel

Safety Objective:
• To evaluate the safety and tolerability of Adex Gel in the treatment of AK

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/06/2026, London - Harrow Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 020 7104 8000; harrow.rec@hra.nhs.uk), ref: 26/PR/0624

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose

Post market clinical follow-up study

Study type(s)

Health condition(s) or problem(s) studied
Actinic keratosis

Interventions
All participants will receive Adex Gel, and will be asked to apply the gel three times daily for 12 weeks. Participants will attend 4 study visits at baseline, 4, 8 and 12 weeks.

Intervention Type
Drug/Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Adex Gel

Primary outcome(s)
1. The severity of actinic keratosis measured using the Actinic Keratosis Area and Severity Index (AKASI) at baseline, 4, 8 and 12 weeks

Key secondary outcome(s)

Completion date
31/03/2027

Eligibility

Key inclusion criteria
A patient must meet all the following conditions to be included in the study:
1. Patient must voluntarily sign and date an informed consent form, approved by a Research Ethics Committee (REC), prior to the initiation of any screening or study specific procedures
2. Adult patient aged ≥18 years
3. Fitzpatrick Skin Phototype I, II, or III (Light to medium skin types characterised by a tendency to burn or sunburn, with limited to moderate tanning ability) as confirmed by the Investigator
4. Has multiple (>1) visible, discrete, AK lesions clinically typical of Olsen grade I or II on any skin areas above the neck
5. Has an AKASI score of between ≥0.8 to ≤6.8
6. Willing to avoid prolonged direct sun exposure, tanning booths, sunlamps, or other UV light sources on the treatment area during the study period
7. Willing to refrain from taking vitamin B3 supplements or oral niacinamide/nicotinamide supplements during the study period
8. Willing and able to understand and comply with all study requirements
9. Willing to avoid the use of new facial personal care products (e.g., make-up, soaps, toners or moisturisers) or change any currently used brands during the study period
10. Patient must be free from any other clinically significant dermatological conditions (other than AK) that may interfere with the study evaluations

11. Patient must be sufficiently proficient in the English language to understand and comply with study

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
A patient will not be permitted to enter the study if any of the following apply:
1. Has a pre-existing facial or scalp dermatologic condition, including those that may be inactive or dormant (e.g., acute skin inflammation, atopic dermatitis, eczema, rosacea, psoriasis, severe acne, seborrheic dermatitis, peri-oral dermatitis, post inflammatory hyperpigmentation or other hyperpigmentation, history of erosive pustular dermatosis) that could interfere with the study evaluations, lesion counts, confound results, or impact patient safety, as assessed and confirmed by the investigator
2. Has very thick, hyperkeratotic, hypertrophic, atypical, or rapidly changing AK lesions (Olsen grade III)
3. Has used topical treatments for AK in the treatment area (e.g., 5-fluorouracil, imiquimod, diclofenac, tirbanibulin, salicylic acid, corticosteroids or retinoids) within 30 days prior to screening
4. Has used chemical peel, dermabrasion, laser therapy, PUVA (psoralen plus ultraviolet A) therapy or UVB (Ultraviolet B) therapy within 6 months prior to screening
5. Has used immunomodulators, systemic chemotherapeutics or immunosuppressive therapies, interferon, oral/injectable corticosteroids, oral retinoids, or cytotoxic drugs within 30 days prior to screening
6. Has diagnosed basal cell carcinoma, squamous cell carcinoma or melanoma
7. Has a history of malignancy not in remission for ≥5 years
8. Has symptoms of clinically significant illness that may influence their participation
9. Has facial hair, abnormal skin pigmentation or body art on the face that may interfere with accurate assessment of AK
10. Has any condition (e.g. xeroderma pigmentosum (XP), albinism, or Bloom’s syndrome) that, in the opinion of the investigator, may influence treatment evaluation or other assessments
11. Has participated in a clinical trial/investigation involving an investigational product (investigational medicinal product/medical device) within 30 days prior to screening
12. Has known hypersensitivity, intolerance, or allergy to Adex Gel or any of its components
13. Is an employee of the investigative site, Sponsor or Clinical Research Organisation (CRO), or a first degree relative of such employees

14. Has an inability to communicate adequately (e.g., language barriers, or neurodevelopmental disorders) in the opinion of the investigator
15. Any other condition that, in the opinion of the investigator, renders the participant unfit for study participation

Date of first enrolment
30/06/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Univ of Nottingham Health Serv
Cripps Health Centre
University Park
Nottingham
England
NG7 2QW

Study participating centre
Burbage Surgery
Tilton Road
Burbage
Hinckley
England
LE10 2SE

Study participating centre
Brierley Park Medical Group, Skegby Site
Mansfield Road
Skegby
Sutton-in-ashfield
England
NG17 3EE

Study participating centre

Chawton Park Surgery
Chawton Park Road
Alton
England
GU34 1RJ

Study participating centre
Beacon Medical Group
Chaddlewood Surgery, 128 Bellingham Crescent
Plymouth
England
PL7 2QP

Study participating centre
Chilwell Valley and Meadows Practice, Chilwell Meadows Surgery
Ranson Road
Chilwell
Beeston
Nottingham
England
NG9 6DX

Sponsor information

Organisation
Dermal Laboratories Ltd

Funder(s)

Funder type

Funder Name
Dermal Laboratories Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available