ISRCTN16168548 https://doi.org/10.1186/ISRCTN16168548

# Efficacy of different photoprotection strategies in preventing actinic keratosis recurrence after photodynamic therapy

**Submission date**
07/05/2018

**Recruitment status**
No longer recruiting

**Registration date**
21/05/2018

**Overall study status**
Completed

**Last Edited**
28/04/2020

**Condition category**
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Actinic keratosis (AK) is a common pre-cancer (with increased risk of developing into cancer) skin change that is caused by due to sun exposure over many years with no sun protection. AK appears as patches of thick, scaly, or crusty skin that feel rough or dry. Several treatments are available for this skin condition. Photodynamic therapy (PDT) using a photosensitizer (a drug that is activated only in the areas of AK using a special type of light), can cure AK patches. After PDT has cleared the AK, patients must protect their skin from the sun to prevent AK coming back. In this study (called ATHENA), we want to test a cream containing sunscreen and piroxicam (a drug that can reduce the risk of skin cancer) in comparison to standard sunscreen-only products in preventing AK coming back after PDT.

Who can participate?
Adults who have at least 6 patches of AK on their scalp or face.

What does the study involve?
All patients will be treated with PDT. They will be randomly allocated to apply to either sunscreen alone or sunscreen containing piroxicam to the affected area twice daily for 6 days.

What are the possible benefits and risks of participating?
If the piroxicam-containing sunscreen is more effective than sunscreen alone in preventing AK coming back, then the participants in this group will benefit from a reduced need for PDT, which can be time-consuming and painful. The standard prevention is to use sunscreen, so participants in the sunscreen-only group will not receive worse treatment than if they were not in the study. There is no increased risk of side effects for the sunscreen containing piroxicam.

Where is the study run from?
Erba-Rinaldi Hospital and DermoLaser Office Verona.

When is the study starting and how long is it expected to run for?
March 2017 to April 2018

Who is funding the study?
The study is funded by Cantabria Labs Difa Cooper, the company that makes the sunscreen containing piroxicam.

Who is the main contact?
Dr Massimo Milani, massimo.milani@difacooper.com

# Contact information

### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
ACTX-01-2017

# Study information

### Scientific Title
The ATHENA Trial: Actixicam after photo-dynamic therapy for multiple actinic keratosis lesions. A randomized open-label assessor-masked outcome evaluation superiority trial vs. standard care in actinic keratosis subjects after phtotodynamic therapies

### Acronym
ATHENA

### Study objectives

After photodynamic therapy (PDT) for multiple actinic keratosis (AK), lesion photoprotection strategies (i.e. use of sunscreen) is mandatory in order to reduce actinic damage and recurrence of new lesions. Recurrence of new AK lesions after PDT are common after 6-9 months after PDT. A sunscreen cream (SPF50+) containing piroxicam 0.8% has shown to be effective in reducing AK lesions as a monotherapy. There are no data comparing different photoprotection strategies (i.e sunscreen only, sunscreen with photolyase etc) comparing the efficacy in reducing AK recurrence after PDT. In this study, we wanted to assess if the use of SPF50+ and piroxicam cream could be more effective than standard photoprotection in reducing recurrence of AK after successful PDT.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
IRB Dermolaser Clinic, Verona, Italy, 15/01/2017, RS: 01-DLC-17

## Study design
Pragmatic randomized open-label assessor-masked trial

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
GP practice

## Study type(s)
Prevention

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Actinic keratosis recurrence after photodynamic therapy

## Interventions
Randomization was performed using a randomization list with an allocation ratio of 1:1.
Actixicam: sunscreen SPF50+ and piroxicam 0.8% cream formulation, applied twice daily 0.5 g (1 finger tip unit) per application for 6 consecutive days after successful PDT
Sunscreen: sunscreen cream (SPF50+ or SPF100+ and photolyase) applied twice daily 0.5 g (1 finger tip unit) per application for 6 consecutive days after successful PDT

## Intervention Type
Drug

## Drug/device/biological/vaccine name(s)
Piroxicam

### Primary outcome measure
Clinical count (assessor masked for allocation treatments) of actinic keratosis lesions 6 months after last PDT session

### Secondary outcome measures
Local tolerability (patient's self-reported complaints e.g. burning, itching etc) will be evaluated at visit 2 (1 month after baseline visit), at visit 2 (3 months after baseline) and at visit 3 (6 months after baseline)

### Overall study start date
01/12/2016

### Completion date
25/04/2018

## Eligibility

### Key inclusion criteria
1. At least 6 AK lesions (scalp or face) suitable for PDT treatment
2. Aged >18 years
3. Willing to participate in the trial (giving written informed consent)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
64 evaluable subject

### Total final enrolment
68

### Key exclusion criteria
1. Other acute skin diseases other than AK
2. Known allergy to one of the components of products used in the trial

### Date of first enrolment
01/03/2017

### Date of final enrolment
30/09/2017

# Locations

### Countries of recruitment
Italy

### Study participating centre
**Erba-Rinaldi Hospital**
Dermatology Unit
Erba-Rinaldi Hospital
Via Casartelli Menaggio
Menaggio
Italy
20126

### Study participating centre
**DermoLaser Office Verona**
Piazza Cittadella
Verona
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# Sponsor information

### Organisation
Cantabria Labs Difa Cooper

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### Sponsor type
Industry

### ROR
https://ror.org/044sr7e96

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Cantabria Labs Difa Cooper

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
25/04/2019

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2019 | 28/04/2020 | Yes | No |