

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

Submission date 07/05/2018	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/05/2018	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 28/04/2020	Condition category Skin and Connective Tissue Diseases	☐ 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

Protocol serial number

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 photodynamic 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
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10090

Sponsor information

Organisation
Cantabria Labs Difa Cooper

ROR
<https://ror.org/044sr7e96>

Funder(s)

Funder type
Not defined

Funder Name
Cantabria Labs Difa Cooper

Results and Publications

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