

Efficacy of Actixicam, a sunscreen with piroxicam, in actinic keratosis

Submission date 22/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/03/2017	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Actinic keratosis (AK) is a common pre-cancerous skin disease. It is more common in those with fair skin and long-term exposure to UV radiation from the sun is considered to be the main risk factor for its development. UV exposure is considered the main risk factor. Dry scaly patches of skin (lesions) develop from years of sun exposure. These lesions are usually harmless and sometimes get better on their own, but they can be sore and itchy. In some cases, they can develop into skin cancer, which can have devastating consequences. Studies have shown that sun protection could reduce the risk of new AK lesions developing. The damage caused to the skin causes an increase cyclooxygenase (COX) 1 and 2 enzymes which are responsible for inflammation (swelling). Anti-COX drugs like diclofenac and piroxicam, applied to the skin, have shown to reduce the number of AK lesions. The aim of this study is to evaluate the efficacy of a skin cream containing sunscreen factors (50+) and piroxicam in the evolution of AK lesions.

Who can participate?

Adults with at least 3 or more AK lesion in sun exposed area

What does the study involve?

Participants are asked to apply the product twice daily in affected area for three months. At the start of the study and then again after three months, participants attend clinic visits at which the number and severity of their AK lesions are assessed.

What are the possible benefits and risks of participating?

The benefit for the patients in participating in the study is performing a sun-protection strategy for at least 3 months which could potentially prevent development of cancer. There are no notable risks involved with participating.

Where is the study run from?

1. Dr Mario Puviani Derma Plus Clinic (Italy)
2. Dr Sergio Pavove Dermatology Clinic (Italy)
3. Dr Galloni, Sant'Agostino Medical center (Italy)

When is the study starting and how long is it expected to run for?
June 2016 to December 2016

Who is funding the study?
Difa Cooper (Italy)

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

Contact information

Type(s)
Scientific

Contact name
Dr Massimo Milani

ORCID ID
<http://orcid.org/0000-0001-7559-1202>

Contact details
Difa Cooper SpA
Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)2965 9031
massimo.milani@difacooper.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ACT03/2016

Study information

Scientific Title
Efficacy of a medical device containing sunscreen and piroxicam in the treatment of actinic keratosis: a multicenter assessor-blinded trial

Study objectives

The aim of this study is to evaluate the clinical efficacy of a film-forming medical device with high sun protection factor (50+) and piroxicam, as first-line treatment in reducing actinic keratosis lesions in subject with actinic damage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medi Plus Dermatological Clinic, 15/05/2015

Study design

Prospective interventional open assessor-blinded non randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Actinic Keratosis

Interventions

All participants are asked to apply the investigational drug (a cream) which contains chemical and physical sunscreen (SPF 50+) and piroxicam 0.8%, twice daily (morning and evening) to face and scalp for three consecutive months.

At baseline and after three months, participants undergo a clinical examination to assess the severity and total number of AK lesions.

Intervention Type

Device

Primary outcome measure

1. Total lesion number of Actinic Keratosis is assessed with a clinical count at baseline and 3 months
2. Dermatoscopy score of target lesion evolution (scoring erythema, scaling, pigmentation, follicular plug) at baseline and 3 months

Secondary outcome measures

1. Severity index of AK lesions is assessed through clinical evaluation by the investigator at baseline and 3 months
2. Investigator Global Index is assessed through clinical evaluation by the investigator at baseline and 3 months

Overall study start date

01/06/2016

Completion date

01/12/2016

Eligibility

Key inclusion criteria

1. At least 3 or more actinic keratosis lesions in a 35 cm² area
2. Age >18 years
3. Fitzpatrick Phototype <III

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Previous treatments for Actinic Keratosis
2. Presence of Non melanoma skin cancer
3. HIV infection or other immunodepression diseases
4. Allergy to piroxicam
5. Pregnancy or breastfeeding

Date of first enrolment

15/06/2016

Date of final enrolment

01/09/2016

Locations

Countries of recruitment

Italy

Study participating centre

Dr Mario Puviani Derma Plus Clinic

Via GL Bernini

Modena

Italy

41121

Study participating centre

Sergio Pavone Dermatology Clinic

Santanna Hospital

Como

Italy

20100

Study participating centre

Dr Galloni, Sant'Agostino Medical center

Sant'agostino Place

Milan

Italy

20126

Sponsor information

Organisation

Difa Cooper SpA

Sponsor details

Via Milano 160

Caronno Pertusella (VA)

Italy

21042

Sponsor type

Industry

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Difa Cooper

Results and Publications

Publication and dissemination plan

The intention is to publish the result in a Pub-med indexed scientific journal.

Intention to publish date

03/03/2017

Individual participant data (IPD) sharing plan

The repository is an Excel file reporting clinical data and outcome data. Participants are coded with progressive numbers in an anonymous form. All participants signed an informed consent prior the enrolment in the trial.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No