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# Efficacy of a sunscreen containing the anti-iflammatory piroxicam in the treatment of early skin cancer

**Submission date**
19/04/2019

**Recruitment status**
No longer recruiting

**Registration date**
30/04/2019

**Overall study status**
Completed

**Last Edited**
05/12/2019

**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 is a early phase of a skin tumor caused by excessive sun exposure. It is known that during AK there is an increase activity of specific enzymes called ciclo-oxygenase (COX1 and COX 2) and this hyperactivity could promote the growth of cancer cells of the skin. Piroxicam is an inhibitor of COX1 and COX 2. Therefore the topical application of piroxicam on the skin with AK could be beneficial in term of reduction of the evolution of the cancer lesion. In this study we want to evaluate the efficacy of a particular sunscreen cream containing piroxicam (an anti-inflammatory agent) in order to treat actinic keratosis lesions on the face. In this trial we also want to evaluate the tumor lesions with a specific high resolution microscope (Reflectance Confocal Microscope) and with dermoscopy.

Who can participate?
Anyone aged over 18, who has multiple actinic keratosis lesions can participate in the study.

What does the study involve?
The study involves subjects with actinic keratosis which are pre-malignant skin lesions due to excessive sun exposure

What are the possible benefits and risks of participating?
The potential benefit for participating subjects is related to the possibility to reduce the evolution of these premalignant skin lesions following the application of a cream with sunscreen action and in addition containing a substance (piroxicam) which could have an anti-inflammatory and anti-tumor actions. No particular risks for the participating subjects are forecasted due to the good safety and tolerability profile of the product which has been used in more than ten thousand subjects so far.

Where is the study run from?
1. Dermatological Clinic Federico II University of Naples, Italy
2. Dermatology Clinic Tor Vergata University Rome, Italy

When is the study starting and how long is it expected to run for?
September 2016 to December 2017

Who is funding the study?
Difa Cooper, Italy

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

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
ACT-03-2016

# Study information

### Scientific Title
Effects of topical piroxicam and sun filters in actinic keratosis evolution and field cancerization: a two-center, assessor-blinded, clinical, confocal microscopy and dermoscopy evaluation trial

### Study objectives
To evaluate in a two-center, prospective trial the effect of a piroxicam-based sunscreen on the evolution of Actinic Keratosis (AK) number, and on confocal microscopy and dermoscopy parameters evolution of a target lesion in subjects with multiple AK lesions.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 20/07/2016, IRB University of Tor Vergata (Ethical committee Università Tor Vergata Viale Oxford 81, Rome, Italy; etico@ptvonline.it) ref: 116/16

## Study design
Prospective assessor-blinded trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Actinic keratosis, in situ skin carcinoma

## Interventions
A Piroxicam-based sunscreen 50+
The intervention involves the application of the evaluated cream twice daily on the target area, using one Finger-Tip-Unit (0.5 g) for the treatment of at least a 35 cm2 area for 6 consecutive months. The study did not include a follow-up evaluation period

## Intervention Type
Device

## Phase
Phase III/IV

## Drug/device/biological/vaccine name(s)
Actixicam MD

## Primary outcome(s)
Clinical evolution of AK lesions number on a target zone area defined as the area with the highest number of AK lesions. Lesion count was assessed with an assessor-blinded approach evaluating digital color high definition images performed at each visit and coded in a blinded fashion at baseline, month 3 (week 12) and month 6 (week 24).

## Key secondary outcome(s))
1. Reflectance confocal microscopy (RCM) calculated assessing 11-item with examination of stratum corneum, granular, spinous and derma layers: Disruption of keratinocytes, Parakeratosis, Polygonal keratinocytes, atypical honeycomb, inflammatory cells, round nucleated cells, curled fibers, collagen alteration, increased vascularity, dermal inflammation, melanophages) at baseline, month 3 (week 12) and month 6 (week 24).
2. Dermoscopy score (DS) features of the target lesion performed assessing erythema, scaling, pigmentation, and follicular plug, using a 5-point score (from 0 to 4 for each item; maximum score: 16) at baseline and month 6 (week 24).

## Completion date
01/04/2018

# Eligibility

### Key inclusion criteria
1. Aged 18 or above
2.Presence of multiple AK lesions on the face or scalp

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
54

### Key exclusion criteria
1. Recently received previous treatments interfering with the evaluation of the treatment area (topical medications, immunosuppressive or immunomodulating agents, phototherapy, oral retinoids, or other therapies for AKs).
2. Pregnant or breast-feeding.

### Date of first enrolment
01/09/2016

### Date of final enrolment
01/12/2017

# Locations

### Countries of recruitment
Italy

### Study participating centre
**Dermatological Clinic Federico II University of Naples**
Via Pansini 5
Naples
Italy
00200

### Study participating centre
**Dermatology Clinic Tor Vergata University Rome**
Viale Oxford 81
Rome
Italy
00100

## Sponsor information

### Organisation
Difa Cooper

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

## Funder(s)

### Funder type
Industry

### Funder Name
Difa Cooper

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Dr Massimo Milani; Massimo.milani@difacooper.com
Type of data: Excel database and GraphPad datasheet
What types of analyses: Descriptive and inferential statistics
Written informed consent was obtained from participants was obtained

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2019 | 05/12/2019 | Yes | No |