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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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available

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 measure

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).

Secondary outcome measures
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).

Overall study start date
01/04/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

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
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Sponsor information

Organisation
Difa Cooper

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Sponsor type
Not defined

Website
difacooper.com

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper

Results and Publications

Publication and dissemination plan
We would like to publish the results of this study in a peer-reviewed international scientific journal

Intention to publish date
01/06/2019

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