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

Submission date
22/12/2016

Recruitment status
No longer recruiting

Registration date
23/12/2016

Overall study status
Completed

Last Edited
31/03/2017

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-cancerous skin disease. It is more common in those with fair skin and long-term exposure to UV raditation from the sun is considered to be the main risk factor for its development. UV exposure is coinsidered 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 otable 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
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Contact information

Type(s)
Scientific

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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 aasked 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
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Study participating centre
Sergio Pavone Dermatology Clinic
Santanna Hospital
Como
Italy
20100

Study participating centre
Dr Galloni, Sant'Agostino Medical center
Sant'agostino Place
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Sponsor information

Organisation
Difa Cooper SpA

Sponsor details
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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 resualt 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