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Use of sunscreens with DNA repair components are more efficacious that sunscreen only in improving keratosis actinica patients clinical outcome after photodynamic therapy

Submission date
04/11/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
29/05/2020

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 keratoses (AK) are dry scaly patches of skin caused by damage from years of exposure to sunlight. Photodynamic therapy (PDT) is a well-established treatment for AK that involves the use of a light-sensitive medication and a light source to destroy abnormal cells. After PDT sun-protection strategies are important in order to reduce the risk of new lesions and/or the need for more PDT. A film-forming medical device containing photolyase, a DNA-repairing enzyme with a light-protective action, has been developed (called Ery).The aim of this study is to assess the clinical effects of Ery in comparison with a commercially available sunscreen (SS) in AK patients after successful PDT for the treatment of AK lesions of the scalp.

Who can participate?
AK patients with at least five AK lesions on the scalp.

What does the study involve?
Participants are randomly allocated to be treated with either Ery or SS. The number of new AK lesions and the need to perform more PDT are evaluated at 1, 3 6 and 9 months after PDT.

What are the possible benefits and risks of participating?
The study products may help in reducing the risk of developing new AK lesions. No specific risks are associated with the use of the two products.

Where is the study run from?
IFO - Regina Elena - San Gallicano Hospital Dermatology and Oncology Division (Italy)

When is the study starting and how long is it expected to run for?
January 2014 to February 2015

Who is funding the study?
IFO Hospital (Italy)

Who is the main contact?
Dr Massimo Milani

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Ery-02-2015

Study information

Scientific Title
A 9-month, randomised, assessor-blinded parallel-group study to evaluate clinical effects of a film-forming medical devices containing photolyase in the treatment of cancerization field in comparison with sunscreen in patients after successful photodynamic therapy for actinic keratosis

Study objectives
To assess and compare the clinical effects of a sunscreen containing a DNA-repair substance on the evolution of actinic keratosis (AK) in comparison with a commercially available sunscreen (SS) in AK subjects after a successful photodynamic therapy (PDT) for the treatment of AK lesions of the scalp.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IFO - Regina Elena - San Gallicano Hospital Rome (Italy), November 2014

Primary study design

Interventional

Study design
Randomised parallel-group assessor-blinded prospective trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Actinic keratosis

Interventions
Patients are randomised to be treated with either:
1. A film-forming class II medical device containing photolyase, a DNA-repairing enzyme, with a high broad photo-protection action (Ery)
2. A commercially available sunscreen

Intervention Type
Device

Primary outcome(s)
Evolution of AK lesions after successful PDT, evaluated at baseline and at 1, 3 6 and 9 months after PDT

Key secondary outcome(s)
Need for additional PDT procedure, evaluated at baseline and at 1, 3 6 and 9 months after PDT

Completion date
02/02/2015

Eligibility

Key inclusion criteria
Presence of at least 5 AK lesions on the scalp

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria

1. Presence of non-melanoma skin cancer lesions
2. Allergy to one of the components of study products
3. Xerodema pigmentosum

Date of first enrolment
01/01/2014

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Italy

Study participating centre
IFO - Regina Elena - San Gallicano Hospital Dermatology and Oncology Division
Rome
Italy
00100

Sponsor information

Organisation
IFO Hospital (Italy)

ROR
https://ror.org/04j6jb515

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IFO Hospital (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	29/05/2020	Yes	No