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	 Prospectively registered Protocol
Registration date 05/11/2015	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 29/05/2020	Condition category Skin and Connective Tissue Diseases	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 sunprotection 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 Dr Massimo Milani

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Study design Randomised parallel-group assessor-blinded prospective trial

Primary study design Interventional

Secondary study design Randomised parallel trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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

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 measure

Evolution of AK lesions after successful PDT, evaluated at baseline and at 1, 3 6 and 9 months after PDT

Secondary outcome measures

Need for additional PDT procedure, evaluated at baseline and at 1, 3 6 and 9 months after PDT

Overall study start date 01/01/2014

Completion date 02/02/2015

Eligibility

Key inclusion criteria

Presence of at least 5 AK lesions on the scalp

Participant type(s) Patient

Age group Senior

Sex Both

Target number of participants 30

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)

Sponsor details

Rome

Italy 00100

Sponsor type Hospital/treatment centre

ROR https://ror.org/04j6jb515

Funder(s)

Funder type Hospital/treatment centre

Funder Name IFO Hospital (Italy)

Results and Publications

Publication and dissemination plan

The plan is to publish the study in a peer-reviewed Journal

Intention to publish date

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