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A study to determine the efficacy of a topically applied artemether gel in the treatment of senile warts.

Submission date
13/02/2015

Recruitment status
No longer recruiting

Registration date
25/02/2015

Overall study status
Completed

Last Edited
15/06/2016

Condition category
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Senile warts are benign skin tumours. They are removed by invasive, unpleasant methods (curettage, cryotherapy, laser, surgery) with certain risks (e.g. infection, depigmentation). This clinical proof of concept study aims to assess the efficacy of an artemether topical formulation in the treatment of senile warts.

Who can participate?
Each participant must have at least 8 flat or slightly elevated senile warts.

What does the study involve?
The test product will be applied twice daily for up to 8 weeks. Five lesions per study participant will be treated with study medication and 3 will serve as reference lesions. The assessment of efficacy will be performed on the photographs taken at the beginning and the treatment and study end by applying a regression score and by measuring the longest axis of lesion.

What are the possible benefits and risks of participating?
The potential benefit for participants is a painless, non-invasive treatment leading to regression or clearance of seborrheic keratosis. Development of adverse events like pruritis, erythema are possible risks associated with the treatment.

Where is the study run from?
The study will be carried out in a dermatology clinic.

When is the study starting and how long is it expected to run for?
From February 2015 to July 2015.

Who is funding the study?
EpiPharm AG

Who is the main contact?
Dr Rosemarie Sift Carter

Contact information

Type(s)
Public

Contact name
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Hauptstrasse 67
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4102

Additional identifiers

Protocol serial number
EPI-02

Study information

Scientific Title
Single centre, open-label, intra-individual, comparison, proof of concept study to determine the efficacy of an artemether topical formulation in subjects with seborrheic keratosis

Study objectives
Treatment of seborrheic keratosis with artemether will lead to regression of the lesions compared to no treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic Committee of North-Western and Central Switzerland, 17/01/2015, reference number: EKNZ 2014-390

Study design
Open-label intra-individual comparison proof-of-concept study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Interventions as of 15/06/2016:
A total of 8 lesions per subject are identified at visit 1 (day 1), 5 of them are allocated to artemether treatment and 3 serve as reference lesions. Artemether 3% is to be administered for a duration of 8 weeks twice daily (i.e. in the morning and evening). The study lesions will be assessed at baseline visit (day 1) and at treatment end and follow-up/study end visits (day 56 and day 85) based on the clinical appearance and the dermoscopic images taken. In addition, the lengths of lesions will be measured at the corresponding visits.

Original interventions:
Topical artemether formulation

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Artemether

Primary outcome(s)
1. Regression of lesions by assessing the lesions with a 6-point IGA (Investigator Global Assessment) Score at baseline, 56 and 85 days
2. Reduction of lesion size by measuring the longest axis (mm) of the lesion at baseline visit (V1) and at baseline, 56 and 85 days

Key secondary outcome(s)
therapy outcome, i.e. the IGA (investigator global assessment) score and lengths of treated lesions versus reference (not treated) lesions at 56 and 85 days.

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Age above 40 years old
2. Phototype II, III and IV
3. At least 8 flat or slightly elevated SK lesions with a “pasted-on” look and typical characteristics
4. Lesion size: longest axis (dimension) 2 mm to 10mm
5. Willingness to participate in the study and to comply with the study protocol
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Presence of pregnancy, lactation, childbearing potential without contraception
2. Female participants of childbearing potential not using and not willing to continue using a medically reliable method of contraception
4. SK lesion close to the eye or mucosa (mouth, genitals)
5. Lesion in a skin fold or an area where clothing (e.g. belt) may cause physical irritation
6. Pedunculated, verrucous, papilomatous and irritated lesions
7. Presence of clinically significant skin or systemic disease
8. Pathological findings at screening (melanoma, lentigo maligna, inflammation, bleeding)
9. Concomitant participation in another study
10. Traveling to regions with endemic malaria
11. Previous use of treatment of the lesions within 2 years prior to visit 1
12. Known or suspected non-compliance, drug or alcohol abuse
13. Inability to follow the procedures of the study, e.g. due to language problems, psychological disorders, dementia, etc. of the participant
14. Enrolment of the investigator, his/her family members, employees and other dependent persons

Date of first enrolment
20/02/2015

Date of final enrolment
30/03/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Somamedica AG
Zollikerstrasse 106
Zollikon
Switzerland
8702

Sponsor information

Organisation
EpiPharm AG

ROR
https://ror.org/040fx6j66

Funder(s)

Funder type
Industry

Funder Name
EpiPharm AG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available