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Treatment of hyperpigmented spots on human skin

Submission date
23/01/2018

Recruitment status
No longer recruiting

Registration date
25/01/2018

Overall study status
Completed

Last Edited
25/01/2018

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
Solar lentigines are patches of darkened skin that us caused by exposure to ultraviolet (UV) radiation. Some people like to try to reduce the look of these spots using treatments to reduce the lesions. This study aims to examine if a new treatment option, using a topical formulation with a new inhibitor of human tryosinase, can reduce the look of the spots.

Who can participate?
Adults aged 50 to 70 years old who have solar lentigines.

What does the study involve?
Participants have one spot treated with a gel formulation containing an new active ingredient to reduce hyperpigmentation and have one spot is treated with the gel but without the active ingredient. The colour, size and the surrounding skin is assessed at four, 8 and 12 weeks after treatment to assess if there is any impact of the two different treatments.

What are the possible benefits and risks of participating?
The active ingredient may reduce the visibility of the hyper pigmented spots. It participants have sensitive individuals, irritation might occur in the treated skin sites.

Where is the study run from?
BDF Test Center (Germany)

When is the study starting and how long is it expected to run for?
March 2012 to November 2012

Who is funding the study?
Beiersdorf AG (Germany)

Who is the main contact?
Dr Ludger Kolbe (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Ludger Kolbe

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ID 41640/ 42307

Study information

Scientific Title
Individuals with solar lentigines on forearm Skin: Does twice daily application of a topical formulation with a new inhibitor of human tyrosinase reduce skin hyperpigmentation?

Study objectives
The tyrosinase Inhibitor W630 reduces hyperpigmentation on human skin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Review Board of Beiersdorf AG, 20/03/2012, ref: ID 41640/42307

Study design
Single center interventional study, vehicle controlled. solar lentigines on volar forearm skin treated twice daily, either with the formulation containing the active ingredient or the basic formulation without the active. Evaluation of skin hyperpigmentation before treatment (baseline) and after 4, 8, and 12 weeeks of Treatment. Comparison (intensity of hyperpigmentation) to baseline and vehicle treated site.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No available in web format, please use the contact details below to request a patient information

Health condition(s) or problem(s) studied
Volar forearms with solar Lentigines, but otherwise healthy skin

Interventions
Participants qualify for study participation by having at least two solar lentigines appropriate for the intended measurements, i.e., suitable in size and coloration. During a two-day preconditioning period, prior to the baseline visit, participants are not allowed to use any moisturizing skin care products on the test sites. At the baseline visit, the color of the spots and the surrounding skin is measured by spectrophotometry. Treatment locations are based upon the positions of the available spots, location of the measured spots is documented by clinical photography. After baseline measurements, the investigator demonstrates correct application of the products with a spot applicator, and trains the participants in self-application. Only the selected spots should to be covered with the product without treatment of the surrounding skin. Each subject treats two spots, one lentiginous spot is treated with a product containing the active ingredient, one spot is treated with vehicle. Treatment is assigned to the individual spots according to a randomization scheme (using Siemens PLM Software Teamcenter 11.2.3.1). For a twelve week treatment period, the participants apply the test products twice daily to the spots on the forearm skin, avoiding the surrounding skin.

Intervention Type
Other

Primary outcome measure
Skin colour contrast of lentigines to surrounding skin is measured using a spectrophotometer at baseline, 4,8, and 12 weeks.

Secondary outcome measures
1. The size and colour of the lentiginous spots is measured using photographs at baseline, 4, 8, and 12 weeks
2. The forearm skin is measured using visual inspections at baseline, 4, 8, 12 weeks for signs of irritation

Overall study start date
15/03/2012

Completion date
13/11/2012

Eligibility

Key inclusion criteria
1. Females/ males between 50 and 70 years of age in generally good health
2. Solar Lentigines on the arms but otherwise healthy, undamaged skin in the test sites
3. Fitzpatrick skin phototype I, II, III or IV
4. Ability to understand the study concept (intellectual capacity and language skills) and to comply with the test schedule and study rules
5. Participant is willing and able to give written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
20 subjects, 15 to conclude the study

Key exclusion criteria
1. Active, acute skin ailments in the test sites, for example atopic Dermatitis or eczema
2. Changes to the skin which conflict with study goals
3. Systemic or topical medication which counteract study objectives
4. Medications, taken either orally or applied topically within the last 4 weeks, which impair immune reactions, for example cytostatic agents and cortisone
5. Severe general illness, either currently or within the last 12 months, for example malignant tumor, severe diabetes, severe cardiovascular disease (e.g. cerebral apoplexy, myocardial infarction, bypass or decompensated high blood pressure)

Date of first enrolment
02/05/2012

Date of final enrolment
21/08/2012

Locations

Countries of recruitment
Germany

Study participating centre

BDF Test Center
Hamburg
Germany
20245

Sponsor information

Organisation
Beiersdorf AG

Sponsor details
Unnastrasse 48
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20245

Sponsor type
Industry

ROR
https://ror.org/04aqg9s78

Funder(s)

Funder type
Industry

Funder Name
Beiersdorf AG

Results and Publications

Publication and dissemination plan
To be published after completing all Tests.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other