

# Treatment of hyperpigmented spots on human skin

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<b>Registration date</b> 25/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/01/2018	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Solar lentigines are patches of darkened skin that are 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 tyrosinase, 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 a new active ingredient to reduce hyperpigmentation and have one spot 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 hyperpigmented spots. In participants who are 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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**Contact details**

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20245

## Additional identifiers

**Protocol serial number**

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 weeks of Treatment. Comparison (intensity of hyperpigmentation) to baseline and vehicle treated site.

**Primary study design**

Interventional

**Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s))**

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

## **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

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

**ROR**

<https://ror.org/04aqq9s78>

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Beiersdorf AG

## Results and Publications

**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