

# Treatment of dark, hyperpigmented patches on human skin

<b>Submission date</b> 01/05/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Melasma is a common pigmentary disorder characterized by hyperpigmented and dark patched skin. Melasma occurs in all populations worldwide and mainly affects adult women with darker skin in their reproductive age living in areas with intense sun exposure. Some people like to try to reduce the look of the patches 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 patches and spots.

### Who can participate?

Women aged 18 to 65 years old who have Fitzpatrick skin type II-IV and who have mild to moderate hyperpigmentation due to melasma on both sides of the face

### What does the study involve?

Participants have one side of their face treated with a formulation containing a new active ingredient to reduce hyperpigmentation and are randomly allocated to either leave the other side of the face untreated or treat the other side of the face with a 2% hydroquinone-containing formulation. Hyperpigmentation is assessed at 4, 8 and 12 weeks after treatment to determine 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 patches. If participants are sensitive individuals, irritation might occur in the treated skin sites.

### Where is the study run from?

Thomas J. Stephens & Associates, Inc., Texas Research Center (USA)

### When is the study starting and how long is it expected to run for?

September 2015 to September 2016

### Who is funding the study?

Beiersdorf AG (Germany)

Who is the main contact?

Dr Ludger Kolbe

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ludger Kolbe

### ORCID ID

<http://orcid.org/0000-0001-8608-8901>

### Contact details

Beiersdorf AG

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20245

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C15-D216 (49595)

## Study information

### Scientific Title

A clinical trial to assess and compare the efficacy and tolerance of two different product formulas used by women with mild to moderate melasma

### Study objectives

The tyrosinase Inhibitor W630 reduces hyperpigmentation on human skin.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

IntegReview Institutional Review Board (IRB) located in Austin, Texas, 12/11/2015, ref: IORG0000689

**Study design**

Single-center double-blinded randomized split-face controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Mild to moderate hyperpigmentation due to melasma on both sides of the face, but otherwise healthy skin

**Interventions**

Prospective subjects are invited to an eligibility screening and advised to avoid application of topical moisturizing products on the face for at least 3 days prior to the screening. At the baseline visit, subjects are clinically graded for overall hyperpigmentation (mottled and discrete), discrete hyperpigmentation, overall appearance, radiance, skin roughness (visual) separately on the right and left sides of the face. Subjects are further assessed for melasma area and severity (MASI) parameters separately on the global right and left sides of the face. A total of two full-face images are taken of each subject (right side and left side views) under standard lighting 1 and 2, and cross-polarized lighting.

Subjects are randomly assigned to cell A or cell B according to a predetermined randomization scheme. Subjects in both cells are distributed a product containing the active ingredient, and subjects in cell B are additionally given an on the market 2% hydroquinone-containing formulation. For a 12-week treatment period, the participants treat one side of the face with the active ingredient formulation twice a day and leave the other side of the face either untreated or treat it twice daily with the 2% hydroquinone-containing formulation.

Evaluation of skin hyperpigmentation before treatment (baseline) and after 4, 8, and 12 weeks of treatment. Comparison (overall and discrete hyperpigmentation, HEMI MASI) to baseline and 2% hydroquinone-treated site.

**Intervention Type**

Other

**Primary outcome measure**

Clinical grading of overall hyperpigmentation (mottled and discrete) and discrete hyperpigmentation (MASI assessment) at baseline, week 4, week 8, and week 12

## **Secondary outcome measures**

Tolerability assessed using a self-assessment questionnaire at baseline, week 4, week 8, and week 12

## **Overall study start date**

11/09/2015

## **Completion date**

29/09/2016

# **Eligibility**

## **Key inclusion criteria**

1. Women 18 to 65 years of age having general good health
2. Fitzpatrick skin type II-IV
3. Individuals with mild to moderate hyperpigmentation due to melasma on both sides of the face (score of 3-6 on according to the modified Griffiths' scale<sup>1</sup>, where 0 = none and 9 = severe, halfpoints are acceptable to qualify)
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

## **Lower age limit**

18 Years

## **Sex**

Female

## **Target number of participants**

60 subjects, 30 per cell

## **Key exclusion criteria**

1. Individuals who had laser resurfacing procedure, deep skin peel, Botox or injection with a dermal filler, or cosmetic procedures on the face within 6 months prior to enrollment
2. Individuals who had used depigmenting products within 2 months prior to enrollment
3. Individuals who have used any topical medications on the face for hyper pigmented lesions or other conditions, or use of photosensitizing medication or procedures (including corticosteroids, hydroquinone, alpha-hydroxy, beta-hydroxy or kojic acid, retinoic acid, retinol, salicylic acid, Vitamin C and Vitamin D preparations or derivatives thereof), bleaching products on the face, UV light therapy, topical prescription treatments, topical tretinoin on the face less than 30 days prior to the study entry
4. Individuals who have used Acitretin, isotretinoin, systemic retinoids (e.g. Accutane), methotrexate, or photoallergic, phototoxic or photo-sensitizing drugs within 6 months of baseline (and will refrain from use during the study)

5. Individuals who have had prior facial microdermabrasion (light or medium skin peel) treatment within 6 weeks prior to study entry.
6. Individuals diagnosed with known allergies to facial skin care products
7. Individuals who are nursing, pregnant, or planning to become pregnant during the study according to subject self-report including those who are not using an acceptable method of contraception throughout the study
8. Individuals with a history of skin cancer
9. Individuals having a health condition and/or pre-existing or dormant dermatologic disease on the face (e.g., psoriasis, rosacea, acne, eczema, seborrheic dermatitis, severe excoriations etc.) that the Investigator or designee deems inappropriate for participation or could interfere with the outcome of the study
10. Individuals with a history of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., zathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or radiation as determined by study documentation
11. Individuals with an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism, or hypothyroidism. Individuals having multiple health conditions may be excluded from participation even if the conditions are controlled by diet, medication, etc

**Date of first enrolment**

20/11/2015

**Date of final enrolment**

08/07/2016

## **Locations**

**Countries of recruitment**

United States of America

**Study participating centre**

**Thomas J. Stephens & Associates, Inc. Texas Research Center**

1801 North Glenville Drive, Suite 200

Richardson

United States of America

75081

## **Sponsor information**

**Organisation**

Beiersdorf AG

**Sponsor details**

Unnastrasse 48  
Hamburg  
Germany  
20245

**Sponsor type**  
Industry

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Beiersdorf AG

## Results and Publications

### Publication and dissemination plan

To be published after completion of all tests. Study protocol and statistical analysis plan will be part of the planned publication.

**Intention to publish date**  
01/10/2018

### Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**  
Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/08/2019	02/03/2022	Yes	No