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Treatment of dark, hyperpigmented patches on human skin

Submission date	Recruitment status	[_] Prospectively registered
01/05/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/03/2022	Skin and Connective Tissue Diseases	

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
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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' scale1, 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
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Sponsor information

Organisation
Beiersdorf AG

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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 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?
Results article		01/08/2019	02/03/2022	Yes	No