ISRCTN33310512 https://doi.org/10.1186/ISRCTN33310512

Efficacy and tolerability of a topical skin-lightening cosmetic product combination on facial dyspigmentation compared with 4% hydroquinone

Submission date
10/12/2018

Recruitment status
No longer recruiting

Registration date
30/01/2019

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Melasma is a common pigmentation disorder characterized by the presence of large irregular brown macules areas in the sun-exposed skin areas, particularly the face and the neck. Hydroquinone is a drug component that has long been the gold standard for the treatment of melasma but its use is compromised due to long-term risks of skin damage. A new skin-lightening combination of cosmetic products (CCP) targeting various steps of the skin pigmentation pathway has been developed. This study aims to evaluate the effectiveness and tolerability of the new CCP compared to hydroquinone 4% in the treatment of facial dyspigmentation.

Who can participate?
Women or men aged between 18 and 60 with a skin phototype IV-V and facial dyspigmentation due to melasma

What does the study involve?
Subjects are randomly allocated to apply on the face, neck and neckline either the combination of cosmetic products (CCP) or 4% hydroquinone cream daily for 12 weeks. The skin is evaluated at the start of the study, week 6 and week 12.

What are the possible benefits and risks of participating?
The study is carried out with cosmetic products whose safety has been assured by the Sponsor. Its aim is to further confirm, under normal and reasonably foreseeable use conditions, the capacity of products to maintain the human body in a good condition and reduce the pigmentation of spots.

Where is the study run from?
Insight Research, a clinical trial organization in Mauritius

When is the study starting and how long is it expected to run for?
January 2018 to May 2018

Who is funding the study?
Isispharma, the company that manufactured the skin-lightening cosmetic product combination

Who is the main contact?
Amélie Clement

Contact information

Type(s)
Scientific

Contact name
Ms Amelie Clement

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17E3927

Study information

Scientific Title
Efficacy and tolerability of a topical skin-lightening CPP on subjects presenting facial dyspigmentation compared with 4% hydroquinone

Acronym
CCP: combination of cosmetic products

Study objectives
The synergetic action of this new topical product combination containing natural extracts and targeting different signaling pathways in melanogenesis could offer an effective and safer alternative to hydroquinone in the management of facial dyspigmentation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Clinical Trials Act 2011 governing clinical trials in Mauritius is not applicable in the case of this study and therefore does not require the authorization of the Competent Authority. However, the study received the approbation of a private and independent ethics committee on 30/01/2018

Study design
Single-centre double-blinded parallel-group randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mild to moderate facial dyspigmentation due to melasma, but otherwise healthy skin

Interventions
Subjects are randomly assigned to one of the two treatment groups.

In the intervention group (CCP group), subjects receive the combination of cosmetic products (CCP): Neotone® serum once daily in the evening and Neotone® Radiance SPF 50+ once daily in the morning.

In the control group (HQ group), subjects receive 4% hydroquinone cream once daily in the evening and an SPF 50+ cream once daily in the morning.

In addition, all the subjects are advised to use a sunscreen without any skin-lightening components, twice daily. All the subjects are instructed to apply the products from baseline for a period of 12 weeks and as recommended by the manufacturer on the face, neck and neckline, avoiding eye area.

Evaluation of the two treatments modalities are performed at baseline, week 6 and week 12 for the following parameters: clinical examination, M-MASI score, colorimetric assessment, facial imaging, tolerability assessment, self-assessment questionnaire.

Intervention Type

Other

Primary outcome measure
1. Clinical scoring of the dyspigmentation with the Modified-MASI score (M-MASI; Dr Amit PANDYA) is performed at baseline, week 6 and week 12
2. Cutaneous color assessed using the Spectrocolorimeter® at baseline, week 6 and week 12
3. Expected visual effect is assessed with photographs taken at baseline, week 6 and week 12
4. Cutaneous acceptability assessed by clinical examination under dermatological control at baseline, week 6 and week 12
5. Cosmetic acceptability and future use is assessed by analysis of the subjects' answers to a subjective evaluation questionnaire at week 6 and week 12

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/01/2018

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Women or men
2. Aged between 18 and 60 years
3. Skin phototype IV-V
4. Presenting facial dyspigmentation due to melasma as determined by Wood's light examination

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44 subjects (22 in each cluster)

Total final enrolment
43

Key exclusion criteria
1. Pregnant or nursing women or women planning to get pregnant during the study
2. Subjects with a cutaneous pathology on the study zone (eczema)

3. Subjects having undergone surgery under general anaesthesia within the previous month
4. Individuals who have been excessively exposed to sunlight or UV-rays within the previous month
5. Subjects having used topical or systemic treatment during the previous weeks liable to interfere with the assessment of the cutaneous acceptability of the study product

Date of first enrolment
22/01/2018

Date of final enrolment
19/02/2018

Locations

Countries of recruitment
Mauritius

Study participating centre
Insight Research
3rd Floor, Orbis Court 132,
St Jean Road
Quatre Bornes
Mauritius
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Sponsor information

Organisation
ISISPHARMA

Sponsor details
29 rue Maurice Flandin
Immeuble le Forum 1er Etage
Lyon
France
69003

Sponsor type
Industry

Website
http://www.isispharma.com

Funder(s)

Funder type
Industry

Funder Name
ISISPHARMA

Results and Publications

Publication and dissemination plan
The study is planned to be published in a peer-reviewed journal.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anne Sirvent (ASI@dermscan.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	19/02/2020	Yes	No