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Comparing the effectiveness of a dermo-cosmetic product vs 4% hydroquinone cream for facial melasma treatment: a controlled clinical study

Submission date
28/10/2024

Recruitment status
No longer recruiting

Registration date
12/11/2024

Overall study status
Completed

Last Edited
12/11/2024

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
Melasma is a common skin condition that affects up to 30% of women and causes dark, symmetrical patches on the face. Often, melasma appears due to pregnancy, hormonal changes, or genetics, especially in people with darker skin tones. Other contributing factors include sun exposure and hormonal treatments like birth control pills. Recently, melasma has also been linked to skin aging, with changes in the skin's structure and blood vessels.
Traditional treatments include depigmenting creams (to lighten dark areas) and sunscreens that protect against different types of light. One well-known treatment, a triple cream combination with hydroquinone, has been effective but can cause side effects like redness, peeling, and burning. Hydroquinone can sometimes cause permanent darkening of the skin, particularly with long-term or high-concentration use, which limits its application. Additionally, hydroquinone has been banned in Europe as a cosmetic ingredient due to health concerns.
This study, funded by a dermo-cosmetic company, ISDIN, aims to evaluate the effectiveness of a new depigmenting serum compared to a 4% hydroquinone cream in treating moderate to severe facial melasma. Neither participants nor researchers know which product is used in each case to avoid bias.

Who can participate?
Women aged 35 to 65 years with melasma

What does the study involve?
Participants are randomly divided into two groups: Group A will use the new depigmenting serum with sunscreen, while Group B will use the 4% hydroquinone cream with sunscreen. Participants will follow this treatment for 120 days, undergoing both clinical and subjective evaluations to assess improvement.

What are the possible benefits and risks of participating?
Participants will have the opportunity to receive a new cosmetic treatment that may be as

effective or more effective than hydroquinone in reducing dark spots. Participants will benefit from detailed and regular medical monitoring throughout the study, providing valuable information about their dermatological health. By participating, volunteers contribute to the advancement of research in treatments for hyperpigmentation and the improvement of cosmetic products. If the cosmetic serum proves to be effective and well-tolerated, it could offer a safer option with fewer side effects than 4% hydroquinone.
Participants may experience allergic reactions or skin irritation from either the new serum or hydroquinone, such as redness, peeling, or itching. The cosmetic serum may not be as effective as hydroquinone, leading to less improvement in the reduction of spots. Participants in the standard hydroquinone group may experience known side effects, including severe irritation, post-inflammatory hyperpigmentation, or unwanted depigmentation. Participants will need to attend follow-up visits and complete assessments throughout the study, which can be a significant time commitment.

Where is the study run from?
Isdin (Spain)

When is the study starting and how long is it expected to run for?
June 2023 to December 2023

Who is funding the study?
Isdin (Spain)

Who is the main contact?
Dr Georgina Logusso, georgina.logusso@isdin.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
EN23-0141-01_ISD-AE-743-07-2023

Study information

Scientific Title
Randomized, double-blind, comparative clinical trial to evaluate the effectiveness of a dermo-cosmetic product versus 4% hydroquinone cream for treatment of facial melasma

Acronym
DERMA

Study objectives
The dermocosmetic product is not inferior to the 4% hydroquinone cream in terms of effectiveness for the treatment of facial melasma

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/06/2023, Universidade São Francisco Research Ethics Committee (Av. São Francisco de Assis, 218, sala 35, prédio central, Sao Paulo, 12.916-900, Brazil; +55 (11)2454-8302; comiteetica@usf.edu.br), ref: 6.155.206

Primary study design
Interventional

Study design
Clinical randomized double-blind and comparative trial

Study type(s)
Safety, Efficacy

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

Interventions
Participants were randomized by simple randomisation using Microsoft Excel into two groups:
Group A: 40 participants used facial serum + facial sunscreen.
Group B: 40 participants used 4% hydroquinone cream + facial sunscreen.

Investigational product:
Apply two doses of the product twice daily (morning and evening) on a clean and dry face, neck and chest, then massage until completely absorbed. Sunscreen should be used in the morning and during exposure to sunlight, and should be applied as soon as the serum is fully absorbed.

Comparator product:
Apply two doses of the product twice daily (morning and evening) on a clean and dry face, neck and chest, then massage until completely absorbed. Sunscreen should be used in the morning and during exposure to sunlight, and should be applied as soon as the serum is fully absorbed.

Sunscreen:
Apply copiously to the skin, 30 minutes before exposure to sunlight. Reapply every 2 hours and after sweating, swimming or toweling.

Participants will follow this treatment for 120 days, undergoing both clinical and subjective evaluations to assess improvement.

Intervention Type
Other

Primary outcome(s)
The non-inferiority of the dermocosmetic product compared to 4% hydroquinone cream in the treatment of facial melasma, measured using the Modified Melasma Area and Severy Index (mMASI) after 30 (D30) and 90 (D90) days of continuous use and 1 month after discontinuation of treatment (D120)

Key secondary outcome(s)
1. The clinical efficacy of products in lightening facial melasma assessed using the Modifed Melasma Area and Severy Index (mMASI) after 30 (D30) and 90 (D90) days of continuous use and 1 month after discontinuation of treatment (D120)
2. The intensity of skin blemishes assessed using the Chromameter® after 30 (D30) and 90 (D90) days of continuous use and 1 month after discontinuation of treatment (D120)
3. The perceived effectiveness of products from the target audience's point of view and the improvement in the quality of life of participants with melasma, measured using the Melasma Quality of Life (MELASQoL) scale and subjective questionnaire after 30 (D30) and 90 (D90) days of continuous use and 1 month after discontinuation of treatment (D120)

Completion date
15/12/2023

Eligibility

Key inclusion criteria
1. Female participants aged from 35 to 65 years old
2. Participants with all skin types (dry, normal, combination or oily)
3. Participants with moderate to severe melasma for at least 1 year, without treatment for at least 3 months (mMASI Scale)
4. User of cosmetic products in the same category
5. Willing to follow the trial procedures and attend the clinic on the days and times determined for evaluations
6. Understanding, consenting and signing the Informed Consent Form (ICF)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
80

Key exclusion criteria
1. Participants who have been diagnosed with COVID-19 by RT-PCR test or by the presence of IgM antibodies in serology test within the last 4 weeks or who are experiencing any of the following symptoms: dry or productive cough, sneezing, runny nose, body pain, headache, anosmia (loss of smell), ageusia (loss of taste) and/or any other symptom that may be related to COVID-19, at the investigator's discretion
2. Pregnancy or at risk of pregnancy/lactation
3. Using anti-inflammatory/immunosuppressive/antihistamine drugs up to 3 weeks before selection
4. Skin spots in the experimental site that interfere with the assessment of possible skin reactions (vascular malformations, scars, increased hairiness, large amounts of nevus, sunburn)
5. History of atopy or allergy to cosmetic products
6. Active skin pathologies and/or lesions (local and/or disseminated) in the assessment site
7. Immunosuppression by drugs or active diseases
8. Decompensated endocrinopathy
9. Relevant medical history or current evidence of alcohol or other drug abuse
10. Known history or suspected intolerance to products in the same category
11. Intense exposure to sunlight up to 15 days before the assessment
12. Aesthetic or dermatological treatment up to 4 weeks before the assessment
13. Other conditions considered by the researcher as reasonable for disqualification from participation in the study (it should be described as observations in the clinical record).

Date of first enrolment
10/07/2023

Date of final enrolment
15/09/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Medcin Instituto Da Pele Ltda
Av. Doutor Carlos de Moraes Barros, 304
Vila Campesina - Osasco

Brazil
06023-000

Sponsor information

Organisation
Isdin (Spain)

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Javier Bustos Santafe (javier.bustos@isdin.com). Individual participant data (in the form of text, tables, figures, and appendices) that underlie the results reported in this article, after deidentification, will be available upon request after publication and ending 36 months after publication. The datasets are stored on spreadsheets and all appropriate requests for appropriate analysis and mechanisms will be considered.
Comments on data anonymization: all data anonymized
Any ethical or legal restrictions: ICH-GCP as well as local applicable regulation

IPD sharing plan summary
Available on request