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A novel rotational combination regimen using different active ingredients to improve facial ageing due to exposure to sunlight and other UV light sources

Submission date
20/04/2020

Recruitment status
No longer recruiting

Registration date
27/04/2020

Overall study status
Completed

Last Edited
12/06/2023

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
Consumers had reported that they were changing products because they felt their skin wasn't continuing to improve as if their skin was 'getting used to their skincare'. The researchers studied the biology of this to determine its accuracy via clinical trial.

Who can participate?
Women in good health and with skin type I-IV who present mild to moderate signs of photodamage on both sides of their faces, scores 3-6 on 0-9 scale (modified Griffiths scale).

What does the study involve?
Subjects will be asked to apply separate treatments to half of their faces on alternating weeks, the other half was untreated. Expert grades, digital images, and self-assessments are collected over 52 weeks.

What are the possible benefits and risks of participating?
Benefits are aging facial improvements. Any signs or symptoms of expected events associated with introducing a new skincare regimen including erythema, dryness, itching, tightness, burning, tingling, or stinging may or may not be coded as adverse events based on the Investigator's assessment. In rare cases, it is possible for a subject to develop allergic reactions to the test material(s)

Where is the study run from?
SGS Stephens Dallas Research Center (USA)

When is the study starting and how long is it expected to run for?
May 2015 to May 2017

Who is funding the study?
Avon Products Inc. (USA)

Who is the main contact?
Lisa DiNatale
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
C15-D199

Study information

Scientific Title
Novel rotational combination regimen to improve facial photoaging: a year-long, split-face, double-blinded clinical trial

Study objectives
Skin gets used to treatment overtime preventing continual aging benefits (i.e. wrinkle reduction) causing a plateau effect. Can rotation of active ingredients 'trick' the skin not allowing for a plateau effect. The clinical trial designed to evaluate the efficacy of the rotational skin care regimen for one year to determine if this regimen would deliver continued improvement over the course of the year.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/10/2015, IntegReview IRB (3815 S. Capital of Texas Hwy, Suite 320, Austin, TX 78704, USA; +1 5123263001; no email provided), ref: C15-D199A

Primary study design
Interventional

Study design
Split-face interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Skin aging

Interventions
Split face 1-year clinical trial, half-face rotating 2 formulas (various active ingredients) every 7 days compared to other side without treatment.
Prior to the start of the study, Stephens Lab will generate a randomization list to establish treatment assignment to the right or left side of the face. The opposite side of the face will remain untreated.

The intervention comprises of two test articles in a suitable cosmetic base: one formulated with cosmetic retinol; the other formulated with a combination of phytol and glycolic acid. Subjects who meet enrollment criteria are instructed to apply the test article to a randomly-assigned half of their face each night, after facial cleansing. Subjects begin by applying the test article with cosmetic retinol during the first week then switch to applying the test article with phytol + glycolic acid for the second week. Subjects continue to alternate (rotate) daily application of the test articles weekly for the ensuing 50 weeks. Subjects also receive a standard facial cleanser and facial sunscreen product to use as needed.

Intervention Type
Other

Primary outcome(s)
Photoaging parameters measured using a modified Griffiths' 10-point scale at baseline, and at weeks 4, 8, 12, 18, 24, 36, and 52
(half-point scores may be used as necessary to more accurately describe the skin condition):
0 = none (best possible condition)
1 to 3 = mild
4 to 6 = moderate
7 to 9 = severe (worst possible condition)

Key secondary outcome(s)
Tolerability evaluations will be performed at baseline, and weeks 4, 8, 12, 18, 24, 36, and 52. Local cutaneous tolerability will be evaluated by assessing the signs and symptoms of erythema, dryness, and edema, and by subject reporting of the degree of burning, stinging, and itching separately on each subject's right and left side of the face (treatment area)

Completion date

01/05/2017

Eligibility

Key inclusion criteria
1. Women in good health
2. Skin type I-IV who presented mild to moderate signs of photodamage on both sides of their faces, scores 3-6 to qualify on 0-9 scale (modified Griffiths scale)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
100

Key exclusion criteria
1. Diagnosed with known allergies to facial skin care products or known sensitivities to facial skin care products, sunscreens, or cleansers.
2. Are nursing, pregnant, or planning to become pregnant during the study according to subject self-report.
3. History of skin cancer.
4. Used any of the following medications or had any of the listed procedures within the listed time frame prior to the study start date:
4.1. Retin-A®, Retin-A Micro®, Renova®, Avita®, Tazorac®, Soriatane®, or Differin® within 4 months
4.2. Had a chemical peel, dermabrasion, non-ablative laser or fractional laser resurfacing of the face and neck within 4 weeks
4.3. Accutane® within 12 months
4.4. Prescription strength skin lightening products (e.g. hydroquinone, tretinoin, AHA, BHA and polyhydroxy acids, 4-hydroxyanisole alone or in combination with tretinoin, etc.) within 4 months
4.5. Any anti-wrinkle, skin lightening products, or any other product or topical or systemic medication known to affect skin aging or dyshcromia (products containing alpha/beta/poly-hydroxy acids, vitamin C, soy, Q-10, hydroquinone; systemic or licorice extract (topically), Tego® Cosmo C250, gigawhite, lemon juice extract (topically), emblica extract, etc.) within 2 weeks
4.6. Have undergone a regimen of Thermage treatments or an equivalent type of high energy treatments, plastic surgery, or ablative laser resurfacing of the face and neck within 12 months
4.7. Had facial treatment with a botulinum toxin base injectable (Botox), injectable fillers, or a fat transfer within 6 months
5. 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.

6. Taking oral to topical antihistamines, anti-inflammatories, or antibiotics. Low-dose aspirin (81 mg daily) is acceptable.
7. Chronic use of systemic steroids within 12 weeks prior to the baseline visit.
8. History of immunosuppression/immune deficiency disorders (including (HIV infection or AIDS) or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or radiation as determined by study documentation.
9. 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.
10. Any planned surgeries and/or invasive medical procedures during the course of the study.
11. Are currently participating in any other facial usage study or have participated in any facial clinical trial at Stephens or at another research facility or doctor's office within 4 weeks prior to inclusion into the study.
12. Have observable suntan, sunburn, scars, nevi, excessive hair, etc. or other dermal conditions on the face that might influence the test results in the opinion of the Investigator or designee.
13. Started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or who plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study.
14. Not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study

Date of first enrolment
11/05/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
United States of America

Study participating centre
SGS Stephens Dallas Research Center
1801 N Glenville Dr suite 200
TX
Richardson
United States of America
75081

Sponsor information

Organisation
Avon (United States)

ROR
https://ror.org/057kqtj87

Funder(s)

Funder type
Industry

Funder Name
Avon Products Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/09/2021	12/06/2023	Yes	No