

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

<b>Submission date</b> 20/04/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/06/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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  
lisa.dinatale@avon.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Lisa DiNatale

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**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

**Study design**

Split-face interventional randomized controlled trial

**Primary study design**

Interventional

**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 dyschromia (products containing alpha/beta/polyhydroxy 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?
<a href="#">Results article</a>		17/09/2021	12/06/2023	Yes	No