

Effect of an antioxidant cosmetic skin cream on healthy participants

Submission date 15/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/06/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2023	Condition category 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

As we age our skin ages, leading to noticeable changes such as wrinkles, dark spots and dryness. It is thought that one of the major causes of skin ageing is sun exposure. When the sun shines on our skin, it produces a dark pigment called melanin which makes us appear tanned while protecting against potentially harmful ultraviolet (UV) rays. Many studies have shown that long-term exposure to UV light causes our skin to age more quickly. It is thought that this is because of a process called oxidative stress, in which free radicals (unstable molecules) attack the DNA of our skin cells, causing them to die. Free radicals are naturally produced as our cells process oxygen however this process is worsened through UV light exposure. Antioxidants are substances which are able to essentially “neutralize” ROS in the body by binding to them so that they are no longer reactive and able to cause damage. There is some evidence to suggest that using skin cream containing antioxidants can help to slow down skin aging. The aim of this study is to investigate the effects of a cosmetic cream which contains antioxidants.

Who can participate?

Healthy Caucasian adults who are showing signs of skin ageing and have not had sun exposure on their backs for at least two months.

What does the study involve?

For all participants, four areas on the left and right legs are randomly allocated to have a different treatment applied every day for 30 days. The first treatment is the test cream, which contains a base with vitamin A, a vitamin E precursor (compound which reacts to form vitamin E) and glyceryl glycolate (a molecule which protects skin tissue from wrinkles). The second treatment is a base cream containing 2% vitamin E. The third treatment is a placebo (dummy) cream which is made up of a base with no active ingredient, and the fourth treatment involves no cream being applied. Participants attend study visits after 15 and 30 days at which UVA radiation is applied to the test areas. Samples are then taken four and 24 hours after the UVA application to measure antioxidant activity and fat breakdown.

What are the possible benefits and risks of participating?

There are no known benefits or risks involved with participating in this study.

Where is the study run from?
Farcoderm facilities, San Martino Siccomario (Italy)

When is the study starting and how long is it expected to run for?
March 2012 to July 2012

Who is funding the study?
Pierre Fabre Dermo Cosmétique (France)

Who is the main contact?
Dr Virginie Ribet

Contact information

Type(s)
Scientific

Contact name
Dr Virginie Ribet

Contact details
Pierre Fabre Dermo Cosmétique
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31025

Additional identifiers

Protocol serial number
RV4400A2011625

Study information

Scientific Title
Placebo/benchmark-controlled, randomized, double blind clinical study aimed to evaluate in situ the antioxidant efficacy of a cosmetic product

Study objectives
The aim of the study is to evaluate the antioxidant efficacy of a cosmetic product in situ.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Single-centre double-blind randomised placebo- and active-controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Antioxidant efficacy of a cosmetic product

Interventions

On each participant, four skin sites on the legs are randomly allocated to receive application of four different treatments daily for 30 days.

Site 1: Test cream, which contains basal cream and 0.1% pre-tocopheryl (vitamin E precursor), 0.1% retinaldehyde (Vitamin A) and 0.1% glyceryl glycineoleamide (GGO: a small amphiphilic molecule that protect the connective tissue of the skin from glycation and elastosis)

Site 2: Basal cream with 2% vitamin E (positive control)

Site 3: Placebo, which contains basal cream without any active ingredient

Site 4: No cream/treatment applied

Participants attend clinic visits at baseline and after 15 and 30 days of treatment. At each visit, participants are exposed to UVA radiation and skin samples are collected on all sites 4 and 24 hours after UVA exposure.

Intervention Type

Other

Primary outcome(s)

Antioxidant activity is measured using Fluorescence Recovery After Photobleaching (FRA) at baseline, 15 and 30 days.

Key secondary outcome(s)

Lipid peroxidation is measured by completing a Lipid Peroxidation (MDA) Assay in each area at baseline, 15 and 30 days of cream application.

Completion date

12/07/2012

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Healthy
3. Caucasian skin type: II, III and IV according to Fitzpatrick classification
4. Showing clinical signs of skin ageing due to physiological ageing (chrono-ageing) and chronological ageing
5. Have not been recently involved in any other similar study
6. Agree to not use during all the study period topic products/dietary supplements with similar effect to that one of the product to be tested (antioxidant)
7. Have not had sun exposure on the back area for at least two months prior to the study

8. Free from of sunburn, suntan, scars, or active dermal lesions on the areas of the back selected for the test purposes
9. Test area must be uniform in colour, without nevi, blemishes or solar lentigo and without hairs
10. Agree not to change the daily routine

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Pregnant or nursing women
2. History of allergies or sensitivity to cosmetic products, toiletries, sunscreens and/or topical drugs
3. Dermatological problems on the test area
4. Under pharmacological treatment (both locally or systemically)
5. Positive anamnesis for atopy (allergic hypersensitivity affecting parts of the body not in direct contact with the allergen)
6. Use of self-tanning products in the previous month after the date of the study
7. Accustomed to using tanning beds
8. Taking medication with photosensitizing potential, drugs and/or dietary supplements able to induce skin colouring, corticoids, currently or during the month before the study
9. Positive anamnesis for atopy (allergic hypersensitivity affecting parts of the body not in direct contact with the allergen)

Date of first enrolment

13/03/2012

Date of final enrolment

30/04/2012

Locations**Countries of recruitment**

Italy

Study participating centre
Farcoderm facilities
Via Mons
Angelini, 21
San Martino Siccomario
Italy
27028

Sponsor information

Organisation

Pierre Fabre Dermo Cosmétique

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Industry

Funder Name

Pierre Fabre Dermo Cosmétique

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/09/2019	10/07/2023	Yes	No