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Effect of an antioxidant cosmetic skin cream on healthy participants

Submission date	Recruitment status
15/01/2016	No longer recruiting
Registration date	**Overall study status**
28/06/2016	Completed
Last Edited	**Condition category**
10/07/2023	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
As we age our skin ages, leading to noticeable changes such as wrinkles, dark spots and dryness. It is though 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 glycyl glycineoleamide (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 take 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

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Pierre Fabre Dermo Cosmétique
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31025

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

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

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

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

Overall study start date
13/03/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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

Sponsor details
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Toulouse
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31025

Sponsor type
Industry

ROR
https://ror.org/04hdhz511

Funder(s)

Funder type
Industry

Funder Name
Pierre Fabre Dermo Cosmétique

Results and Publications

Publication and dissemination plan
Planned publication in JAMA Dermatology in 2016

Intention to publish date
30/01/2016

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