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A randomized, double-blind, placebo-controlled study to investigate the effects of OmniActive Lutemax 2020® oil suspension on skin health attributes

Submission date
31/07/2015

Recruitment status
No longer recruiting

Registration date
24/08/2015

Overall study status
Completed

Last Edited
31/07/2018

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
Lutein and zeaxanthin are naturally occurring compounds called carotenoids. They have both been shown to reduce the risk of cataracts and age-related macular degeneration (a condition whereby the sufferer loses their central vision, usually gradually over a period of time). Lutemax™ 2020 is a product enriched with lutein and zeaxanthin taken from Marigold flowers. This study investigates the effects of Lutemax™ 2020 (10 mg/day) when compared to a placebo for 12 weeks on the skin including lightening, hydration, roughness levels and elasticity and also to study its effects on photo damage.

Who can participate?
Adults aged 18-45 with certain skin tones and happy to follow the dietary restrictions involved.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given a dietary supplement containing carotenoids (Lutemax™ 2020 containing 10 mg L and 2 mg Zeaxanthin isomers) or a placebo (safflower oil) taken orally (with water, after breakfast) once a day. Skin health attributes will be measured such as skin color, skin tone, hydration and elasticity are then measured for all participants in each group and compared.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
TKL Research Center, New Jersey, USA

When is the study starting and how long is it expected to run for?
March 2014 to February 2015

Who is funding the study?
OmniActive Health Technologies Inc.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OAHT002-2013 (CS920113)

Study information

Scientific Title
The effects of oral supplementation of lutein and zeaxanthin isomers (Lutemax2020®) on skin color and skin tone: a double-blind and placebo-controlled clinical trial

Study objectives
Carotenoids especially lutein and zeaxanthin isomers (RR-zeaxanthin and RS-zeaxanthin) possess absorption spectra in both in the UVB and UVA range, and are able to block the formation of melanin pathways and melanin in melanocytes, decreases inflammatory cytokines and increases anti-oxidant properties. Lutein is one of the carotenoids that is present in high concentrations in

skin cells. Hence we examined the effects of lutein and zeaxanthin isomers effect on skin color and skin tone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IntegReview (USA), 03/02/2014, ref: OAHT002-2013 (TKL No. CS920113)

Study design
Randomized double-blind matched-pair placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

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

Interventions
Lutemax2020® (containing 10 mg lutein and 2 mg zeaxanthin isomers) or a placebo (safflower oil) taken orally once a day.

Intervention Type
Supplement

Primary outcome measure
1. Skin color
2. Skin tone
3. Photoprotective activity
4. Hydration
5. TEWL
6. Subjective assessments for skin health

Secondary outcome measures
Blood analysis such as lutein and zeaxanthin isomers

Overall study start date

30/03/2014

Completion date
15/02/2015

Eligibility

Key inclusion criteria
1. Healthy, pre-menopausal females aged 18 to 45 years
2. Healthy males aged 18-45 years
3. Subjects with mild to moderate dry skin (to be determined by the Investigator).
4. Fitzpatrick Skin Type II –IV scale
5. Non-smokers
6. A body mass index (BMI) of 20 to 34 kg/m2
7. Normal values, based on the opinion of investigator, for the following assays: clinical chemistry, hematology, and urinalysis
8. Willing to avoid lutein/zeaxanthin rich foods and follow the dietary restriction list provided by the PI during the study and for 10 days prior to enrollment
9. Subjects are willing to avoid prolonged exposure to UV radiation and sun bath for the duration of the study
10. Willingness to complete all clinic visits and to complete all diaries/records associated with the study
11. Willingness to avoid cosmetics (excluding sunscreen) and cosmetic procedures (i.e., chemical peels, microdermabrasion, laser treatment) that may affect the skin on the forearms and face.
12. Willingness to use only the provided body wash and body cream for the entire 12-week study duration and to follow specific instructions related to their use on study visit days. Continued use of current facial moisturizers and cleansers will be acceptable but cannot contain alpha-hydroxy acids, salicylic acid, vitamin C, retinol and retinoid
13. Able to provide informed consent
14. Willingness not to apply regularly used make-up during each study visit

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
48

Key exclusion criteria

1. Subjects with moderate or severe acne.
2. Subjects who have participated in a clinical study in which they used Retin-A or a retinoid, alpha-hydroxy acids, salicylic acid or vitamin C for 3 months prior to enrollment.
3. Subjects currently using any topical medication on the face. Continued use of current facial moisturizers and cleansers will be acceptable but cannot contain alpha hydroxy acids, salicylic acid, vitamin C, retinol and retinoid.
4. History of, or current disease or condition of the skin that the investigator deems inappropriate for study participation (eg, atopic skin, acne vulgaris, facial scars, psoriasis, eczema, other scaly inflammatory diseases).
5. History of, or current diagnosis of uncontrolled chronic conditions eg liver, kidney, pulmonary, gastrointestinal, cardiovascular, pancreatic and/or immune diseases[1] (3 months on stable pharmacological treatment is acceptable).
6. History of, or current diagnosis of, cancer[1].
7. Diagnosed with hyperthyroidism or hypothyroidism[1].
8. Positive narcotics (urinalysis) or alcohol screen (breathalyzer).
9. Subjects who have had a facial cosmetic procedures (eg, fillers, toxins, facial peel) or invasive surgical procedures (eg, laser treatment or face lift) or other facial treatments by a physician or skin care professional within the last 6 months from baseline or plan to have a treatment during the study.
10. Subjects using an alpha-hydroxy acid containing products within 3 months of enrollment. Continued use of current facial moisturizers and cleansers will be acceptable, but cannot contain alpha-hydroxy acids, salicylic acid, vitamin C, retinol and retinoid.
11. Subjects currently using a salicylic acid containing product on the face (including astringents and toners) 3 months prior to enrollment. Continued use of current facial moisturizers and cleansers will be acceptable but cannot contain alpha-hydroxy acids, salicylic acid, vitamin C, retinol and retinoid.
12. Subjects currently using or have used products containing retinol or retinoid on the face (including moisturizers) 3 months prior to enrollment. Continued use of current facial moisturizers and cleansers will be acceptable, but cannot contain alpha-hydroxy acids, salicylic acid, vitamin C, retinol and retinoid.
13. Subjects currently under a physician’s care for a skin problem.
14. Taking any medication that could affect skin (eg, Tetracycline).
15. Recent sunburn or having peeling due to sunburn within 2 weeks of enrollment.
16. Taking vacation involving photo exposure (beaches or skiing) during the study.
17. Subjects have used tretinoin, adapalene, tazarotene or other topical retinoid medications for the treatment of facial skin aging 3 months prior to enrollment and during the study.
18. Subjects have used or plan to use systemic corticosteroids within 30 days of enrollment or during the study.
19. Use of any dietary supplement, over-the-counter or prescription product with the indication of improving the appearance or condition of the skin (eg, antioxidants, anti-aging retinoids, antibiotics, corticosteroids) within one month of enrollment.
20. Subjects have a history of severe alcohol consumption or drug abuse in the past year (obtained through Medical History).
21. Subjects are participating in another interventional study.
22. Positive pregnancy test in women of child-bearing potential.
23. Pregnant or breast-feeding or planning on becoming pregnant.
24. Women of child-bearing potential not using effective non-hormonal contraception.
25. Use of lutein supplements or multivitamin supplements or cosmetics containing lutein or multivitamin providing more than 1 mg of lutein per day within 10 days of enrollment.

Date of first enrolment

30/03/2014

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United States of America

Study participating centre
TKL Research Center
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Sponsor type
Industry

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ROR
https://ror.org/024e1pj18

Funder(s)

Funder type
Industry

Funder Name
OmniActive Health Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date
30/12/2015

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	results	07/10/2016		Yes	No