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The evaluation of the effect and safety of night serum in visible signs of aging

Submission date
31/10/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
04/11/2019

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The skin loses its structure and functionality as we age. This is caused by different factors like metabolic aging and oxidative stress caused by UV light and pollution. A night serum contains antioxidants and ingredient that improves skin's elasticity and firmness. The aim of this study is to evaluate the anti-aging effect of the night serum in the improvement of the clinical signs of skin/facial aging.

Who can participate?
Healthy volunteers (men and women), aged between 40 and 75 years old with moderate skin aging

What does the study involve?
Participants use the serum every night for 12 or 24 weeks (depends on the site) on the face, neck and neckline. Doctors evaluate their skin before and after (at 6, 12, 18 and 24 weeks) the use of the product and take photographs of the face. Participants are also asked to evaluate their skin condition and quality of life at the same timepoints. Participants in the biopsy study have biopsies (samples) taken from the forearm (at site 1) or from the neck (at site 2).

What are the possible benefits and risks of participating?
The potential benefit of participating is an improvement in the appearance of the face, neck and neckline. The potential risk is discomfort on the skin. For participants having biopsies potential risks are the ones related to this kind of procedure.

Where is the study run from?
1. Skin Laser & Surgery Specialists, Hackensack, NJ (USA)
2. Modern Dermatology, Westport, CT (USA)

When is the study starting and how long is it expected to run for?
June 2018 to July 2019

Who is funding the study?
ISDIN

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ISD-AE652-01-2018

Study information

Scientific Title
Multicenter, open-label, clinical study evaluating the efficacy and safety of an antiaging night serum product applied once daily for improvement of visible aging signs in healthy subjects with moderate facial aging

Study objectives
The aim of this study was to evaluate the anti-aging efficacy of the serum containing melatonin, bakuchiol and vitamin C with other ingredients that provide deep nourishment.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 05/07/2018, Allendale Investigational Review Board (30 Neck Road, Old Lyme, CT 06371, USA; Tel: +1 (0) 860 434 5872)
2. Approved 09/10/2018, U.S. Investigational Review Board Inc (6400 SW 72 Court, Miami, Florida 33143, USA; Tel: +1 (0)786 473 3095), ref: U.S.IRB2018MD/01

Study design
Multicentre prospective open-label trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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 with moderate signs of aging

Interventions
Subjects were instructed to use the serum once a day at night on the face, neck and neckline for 12 weeks. On site n#2 subjects participated in an extension period to 24 weeks.

Efficacy assessments were conducted on week 6, 12, 18 and 24 (standardized photos, expert investigator grading, subjects reported outcome measures).

Skin biopsies were collected from the arms (treated and untreated arm) at baseline and Week 12 at site#1 and the neck (baseline and treated sun-exposed area) at baseline and Week 24 at site#2.

Intervention Type
Other

Primary outcome measure
Signs of aging considering separately each sign graded by the investigators scale (radiance, skin texture/smoothness, pigmentation, erythema, pore size, skin tone, skin complexion, lines, wrinkles and youthful appearance) at baseline, Week 6, Week 12, Week 18 and Week 24

Secondary outcome measures
1. Change in overall fine lines, wrinkles, hyperpigmentation and erythema measured using Investigator Global Aesthetic Improvement Scale (GAIS) evaluated by investigator at baseline, Week 6, Week 12, Week 18 and Week 24
2. Change in radiance, skin texture/smoothness, pigmentation, erythema, pore size, skin tone,

skin complexion, lines, wrinkles and youthful appearance measured using Skin Quality Assessments scale evaluated by investigator at baseline, Week 6, Week 12, Week 18 and Week 24
3. Photodamage and hyperpigmentation measured using the Investigator Global Assessment (IGA) scale evaluated by investigator at baseline, Week 6, Week 12, Week 18 and Week 24
4. Change in signs of facial aging measured using Wrinkle Severity Scale evaluated by investigator at baseline, Week 6, Week 12, Week 18 and Week 24
5. Change in overall fine lines, wrinkles, hyperpigmentation and erythema measured using Subject Global Aesthetic Improvement Scale (SGAIS) evaluated by subject at baseline, Week 6, Week 12, Week 18 and Week 24
6. Change in lines/wrinkles, spots, redness, firmness, radiance/luminosity and skin texture /smoothness measured using Standardized digital images captured with VISIA or standardized system evaluated at baseline, Week 6, Week 12, Week 18 and Week 24
7. Local (dermal) tolerability examination on investigational areas including assessments of stinging/burning (rated by the subject), dryness, scaling, edema and erythema (rated by the investigator). It will be evaluated by grading from 0 (None) to 3 (Severe) at all study visits
8. Adverse events, including the seriousness, grade and causal relationship with IP as per adverse event standard criteria, recorded in the CRF on Week 6, Week 12, Week 18 and Week 24

Overall study start date
07/06/2018

Completion date
11/07/2019

Eligibility

Key inclusion criteria
1. Healthy females and males who are regular users of serum products
2. Age: between 40 and 75 years old inclusive at enrollment
3. Subjects with moderate skin aging
4. Subjects with Fitzpatrick photo skin types I-V
5. Subjects will be able to read, understand and sign an informed consent form
6. Willing to be photographed and sign photograph (model) release form
7. Subject willing to adhere to the protocol and study procedures
8. Subjects who agree not to have any procedures affecting facial wrinkles or skin quality (Ex. microdermabrasion, peels, acne treatments, filler, botulinum toxin, radiofrequency, laser, IPL, ultrasound) for the duration of the study
9. Subjects try to follow a daily facial routine
10. Subjects are willing and able to follow all study assessments, attend study visits as scheduled and must be willing to accept the restrictions of the study, including but not limited to:
10.1. Arrive at each visit with clean facial skin, having cleansed within one hour of the study visit and having applied no topical products
10.2. Refrain from using self-tanning products on the face and body for the duration of the study
10.3. Refrain from excessive sun exposure or artificial UV tanning for any purpose for the duration of the study
10.4. Fotoprotector 50+ must be used in case of sun exposure

Participant type(s)
Healthy volunteer

Age group

Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Subjects having an acute or chronic disease or medical condition, including dermatological problems, which could put them at risk in the opinion of the Principal Investigator or compromise study outcomes
2. Subjects who are unreliable or unlikely to be available for the duration of the study
3. Subjects with a history of allergic reactions, skin sensitization and/or known allergies to cosmetic ingredients, toiletries, sunscreens, etc
4. Immunocompromised subjects
5. Subjects who started Hormone Replacement Therapy within the last three months preceding the screening visit
6. Subjects using oral contraception for less than 3 months before the screening visit or who has changed contraceptive method within the 3 months before the Baseline visit or planning to modify contraception treatment within the duration of the study
7. Subjects who are pregnant, breastfeeding or planning to become pregnant within 6 months
8. Subjects who have been treated with botulinum toxin in the face in the past 6 months
9. Subjects who have had treatments with hyaluronic acid, CaHA or poly-L-lactic acid fillers in the face in the last 24 months
10. Subjects who have had treatments with PMMA or any permanent filler in the face at any time
11. Subjects who have had a surgical procedure of the face, including face lift, blepharoplasty, etc. at any time
12. Subjects who have had any kind of facial dermabrasion, chemical peel, laser, IPL or any other treatment that could influence the skin quality in the past 3 months or for the duration of the study
13. Subjects who have had systemic corticosteroid therapy or any other therapy with influence on the skin quality in the past 6 months or for the duration of the study
14. Subjects who have used a topical, retinoid, retinol, or retinol derivative or topical antioxidant within the last 30 days
15. Subjects who does not agree to avoid using tanning beds or intensive exposure to the sun for the duration of the study and within two weeks of initiating participation
16. Subjects who have participated in another research study in the past 15 days
17. Individuals unable to communicate or cooperate with the Principal Investigator due to any reason deemed by the PI
18. Patients with marked photodamage with apparent precancerous or cancerous lesions
19. Patients unwilling to stop other topical facial products, with the exception of sunscreen, for the duration of the study, except as those defined that may be used

Date of first enrolment
02/08/2018

Date of final enrolment
17/01/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Skin Laser & Surgery Specialists
20 Prospect Ave #702
Hackensack
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Sponsor information

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Sponsor type
Industry

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A.

Results and Publications

Publication and dissemination plan

The researchers intend to publish the study results in an international peer-reviewed indexed scientific journal. Additional documents are not published online.

Intention to publish date
15/12/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication. Written informed consent from participants was obtained.

IPD sharing plan summary
Other