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Use of melatonin, oral and cream, to counteract skin ageing: a controlled trial

Submission date
20/01/2025

Recruitment status
No longer recruiting

Registration date
21/01/2025

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Skin ageing is a complex process influenced by intrinsic factors, such as genetic predisposition, and extrinsic factors, including UV radiation and environmental pollution. Melatonin, a hormone known for its role in regulating circadian rhythms, has gained attention in dermatology for its potential anti-ageing properties due to its antioxidant and skin-repairing effects. Topical melatonin-based treatments have shown promise in improving signs of skin ageing, including elasticity, wrinkles, and pigmentation. However, no clinical studies have evaluated the combined ("In&Out") approach of using a topical melatonin-based cream alongside a melatonin-containing oral supplement enriched with hyaluronic acid and apigenin, both of which are recognized for their anti-ageing and skin hydration properties. Understanding the synergistic potential of this regimen could offer new insights into more comprehensive anti-ageing strategies.
This study aims to compare the effectiveness of two skin anti-ageing strategies: the use of a melatonin-based topical cream alone and a combined regimen of the same melatonin-based cream and a melatonin-based oral supplement containing hyaluronic acid and apigenin. The primary objective is to assess changes in skin ageing signs over a 12-week period. Secondary objectives include evaluating specific skin parameters and conducting VISIA imaging analysis to further explore the potential added benefit of the combination therapy compared to topical treatment alone.

Who can participate?
People aged over 50 years with moderate-severe skin ageing (Glogau score >2)

What does the study involve?
The study involved two melatonin-based products, one melatonin-based cream and a food supplement containing melatonin, apigenin and hyaluronic acid. Participants were randomly allocated to one of two groups. They were instructed to apply the cream twice a day for group A, and the cream twice per day plus one tablet of the food supplement per day for group B. The total duration of the treatment was 12 weeks with three measurements at the start and after 6 and 12 weeks.

What are the possible benefits and risks of participating?
The possible benefit is the improvement of skin health and skin ageing. There are no risks because of the use of already approved cosmetic products using well-known ingredients.

Where is the study run from?
Difa Cooper (Italy)

When is the study starting and how long is it expected to run for?
June 2023 to April 2024

Who is funding the study?
The study was founded by an unrestricted grant from Cantabria Labs Difa Cooper (Italy)

Who is the main contact?
Dr Massimo Milani, massimo.milani@difacooper.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Massimo Milani

ORCID ID
http://orcid.org/0000-0001-7559-1202

Contact details
Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)29659031
massimo.milani@difacooper.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Skin anti-aging effect of a melatonin-based in&out strategy in comparison with topical treatment alone: a randomized, assessor-blinded, prospective trial with VISIA evaluation

Study objectives
To evaluate if an "In&Out" strategy with a melatonin-based dietary supplementation plus melatonin cream-based treatment was superior to melatonin-based cream only on skin aging.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The present trial was performed using a cosmetic and a food supplement. Therefore according to the current national legislation, a formal EC approval is not required. However, the present trial was performed according to Helsinki's ethical principles. Each subject signed an informed consent.

Study design
Randomized prospective assessor-blinded interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Available on request

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

Interventions
"Out" strategy: Melatonin-based cream 0.1%
"In" strategy: Mel-based (0.5 mg) dietary supplementation also containing hyaluronic acid (150 mg; HA) and apigenin (0.9 mg)

Participants were randomized in a 1:1 allocation ratio. They were also instructed to apply the cream twice a day using 2 ftu (fingertips units) for group A and the cream twice per day using 2 ftu plus one tablet of the food supplement per day for group B. The total duration of the treatment was 12 weeks with three measurements (baseline, t6 and t12) and two timepoints at 6 and at 12 weeks.

Intervention Type
Mixed

Primary outcome measure
Elasticity, wrinkles, roughness, pigmentation, erythema, and skin pores assessed using the Skin Aging Global Score (SAGS) at baseline, week 6 and week 12

Secondary outcome measures
1. Clinical evaluation of Skin ageing using the Glogau score at baseline, week 6 and week 12
2. Single parameters of SAGS measured at baseline, week 6 and week 12
3. Instrumental skin ageing evaluation using VISIA objective face sculptor analysis performed on a subgroup of 20 participants at baseline, week 6 and week 12

Overall study start date
01/06/2023

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Women with moderate/severe skin ageing defined as a Glogau Score higher than II

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
50 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
50

Total final enrolment
46

Key exclusion criteria
Skin acute conditions like eczema or skin cancer

Date of first enrolment
01/09/2023

Date of final enrolment

01/02/2024

Locations

Countries of recruitment
Italy

Study participating centre
Difa Cooper Medical department
Via Milano 160
Caronno Pertusella
Italy
21042

Study participating centre
Skin Center Clinic Modena
Via G. Zattera 130
Modena
Italy
41124

Sponsor information

Organisation
Difa Cooper (Italy)

Sponsor details
Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)29659031
massimo.milani@difacooper.com

Sponsor type
Industry

Website
http://www.difacooper.com/

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper

Results and Publications

Publication and dissemination plan
Planned publication in an international peer-reviewed journal

Intention to publish date
30/03/2025

Individual participant data (IPD) sharing plan
Dataset will be available on request from Dr Massimo Milani (massimo.milani@difacooper.com)

IPD sharing plan summary
Available on request