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Skin enhancement and skin repair efficacy clinical study

Submission date
18/06/2025

Recruitment status
No longer recruiting

Registration date
30/06/2025

Overall study status
Completed

Last Edited
25/06/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
Ablative fractional CO2 laser treatment (AFCO2) can cause immediate erythema (skin redness), pain, and complications like prolonged erythema and post-inflammatory hyperpigmentation (skin darkening). This study investigated whether the use of a serum before and after AFCO2 could accelerate skin recovery and relieve complications.

Who can participate?
Healthy Chinese women aged 20-50 years with acne scars who intend to undergo AFCO2

What does the study involve?
Participants were randomly allocated to either the facial serum group or the non-treatment group. The participants in the facial serum group applied the study serum for 2 weeks in the pre-operative and post-treatment stages, with additional product usage for all participants (both groups) of standard products, including standard cleanser, moisturiser and sunscreen. Trans-epidermal water loss, skin hydration, and skin qualities were evaluated during the whole study.

What are the benefits and risks of participating?
The serum may speed up postoperative recovery and reduce postoperative erythema and discomfort, enhancing the effectiveness of and satisfaction with AFCO2 treatment.

Where is the study run from?
L'Oréal Research and Innovation (China)

When is the study starting and how long is it expected to run for?
December 2021 to January 2022

Who funded the study?
L'Oréal Research and Innovation (China)

Who is the main contact?
1. Li Jing, amy.li@loreal.com
2. Liu Xingzuo, xingzuo.liu@loreal.com

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CN-CLI-21-14049-46

Study information

Scientific Title
Efficacy and tolerability of a facial serum before and after ablative fractional carbon dioxide laser: a randomized controlled trial on Chinese women

Study objectives
It was hypothesized that the use of the serum before AFCO2 treatment could help minimize the damage caused by the treatment and thus promote faster and better postoperative recovery of the skin. Therefore, this study aimed to evaluate whether the use of the serum before treatment could contribute to a quicker recovery after AFCO2 treatment and whether the use of the serum during the post-treatment period could help with skin recovery and discomfort relief.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/12/2021, Shanghai Ethics Committee For Clinical Research (Building 10, No. 140 Tianlin Road, Shanghai, 200233, China; +86 (0)21 33676540; hongxia.zhang@scrcnet.org), ref: SECCR/2021-180-01

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Pharmaceutical testing facility

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Repair efficacy of skin barrier and condition

Interventions
70 female adults will be enrolled and divided into two groups in the study, recruited according to inclusion and non-inclusion criteria listed below, and at least 60 should complete the whole study (at least 30 per group):
Group 1: Facial serum group
Group 2: Non-treatment group

The participants in the serum group applied the study serum for 2 weeks in the pre-operative stage (D0 and D14), and post-treatment stages (D32 and D39), with additional product usage for all participants (both groups) of standard products, including standard cleanser, moisturiser, and sunscreen.

Test Duration: 9 visits in 39 days (7 days for washout, 14 days for pre-treatment, 1 day for chemical procedure, 1 day self-recovery, 3-day self-recovery, 7-day self-recovery, 10-day skin self-recovery and 14 days post-treatment).
Visit 1: T-7d
Visit 2: T0 (baseline)
Visit 3: T14d (14 days after pre-treatment)
Visit 4: T15d (chemical procedure and Timm post-procedure)
Visit 5: T16d (1 day after self-recovery)
Visit 6: T18d (3 days after self-recovery)
Visit 7: T22d (7 days after self-recovery)
Visit 8: T25d (10 days after self-recovery and product treatment start)
Visit 9: T32d (7 days after product treatment)
Visit 10: T39d (14 days after product treatment)

Intervention Type
Other

Primary outcome measure
1. Clinical assessment: skin qualities of skin dryness, erythema, papules, desquamation, chromatosis, edema, escharosis, elasticity, evenness, brightness, radiance, smoothness, pores on cheek, crow's feet wrinkle, epithelial confluence and overall healthy appearance will be evaluated by dermatologist at T0 (baseline), T14d (after pre-treatment), T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.
2. Sensitivity measured using the lactic acid stinging test at T0 (baseline), T14d (after pre-treatment), T25d (10 days after self-recovery and product treatment start), T39d (14 days after product treatment) for all groups.
3. Skin hydration measured using a corneometer at T0 (baseline), T14d (after pre-treatment), T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.
4. Transepidermal water loss (TEWL) measured using a vapometer at T0 (baseline), T14d (after pre-treatment), T15d (Timm postprocedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.
5. Skin elasticity (R2, R5, R7) measured using a cutometer at T0 (baseline), T14d (after pre-treatment), T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.
6. Skin pH value measured using a pH meter at T0 (baseline), T14d (after pre-treatment), T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.

7. Photo capture and imaging analysis:
7.1. VISIA 7: standard facial photo shooting will be done at T0 (baseline), T14d (after pre-treatment), T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery and product treatment start), T32d (7 days after product treatment), T39d (14 days after product treatment) for all groups.
7.2. OCT: standard facial scan will be done at T0 (baseline), T14d (after pretreatment), T15d (Timm post-procedure), T16d (1-day after self-recovery), T18d (3-day after self-recovery), T22d (7-day after self-recovery), T25d (10-day after self-recovery and product treatment start), T32d (7-day after product treatment), T39d (14-day after product treatment) for all groups.

Secondary outcome measures
1. Product efficacy assessed using self-assessment questionnaire at T14d (after pre-treatment), T25d (10 days after self-recovery), T32d (7 days after product treatment), T39d (14 days after product treatment) for Group 1 (n = 30)
2. Cosmeticity assessed using self-assessment questionnaire at T14d (after pre-treatment), T39d (after product treatment) for Group 1 (n = 30)
3. Post-procedure tolerance assessed using self-assessment questionnaire at T15d (Timm post-procedure), T16d (1 day after self-recovery), T18d (3 days after self-recovery), T22d (7 days after self-recovery), T25d (10 days after self-recovery) for all groups (n = 60)

Overall study start date
08/12/2021

Completion date
28/01/2022

Eligibility

Key inclusion criteria
1. Chinese women, 20-50 years old
2. All skin types (dry, normal, oily and mixed)
3. No high risk of hyperpigmentation skin (adjusted by the Hyperpigmentation skin questionnaire, refer to Annex 11.2)
4. Rough and dull skin (self-declared)
5. Lack of radiance, brightness, smoothness by self-claimed
6. Presenting with problems of acne marks, acne scars or blemishes on the face
7. Did not participate in any clinical test or cosmetic product test on skin within 3 months
8. Did not participate in any chemical procedures for the previous 2 months and is willing not to participate in any procedures during the whole study
9. No disagreement of the dermatologist because of other reasons that exclude the participation of the volunteer
10. In good general health at the time of the study
11. Willing and able to participate as evidenced by the signing of informed consent
12. Willing and able to participate in the assigned chemical procedure and apply the assigned products
13. Must be willing to comply with all study protocol requirements (pay attention to: only use the skin care products provided during the study, not take topical or oral treatment like retinol, hormone, anti-oxidant health-care products which may affect the anti-ageing efficacy of test serum)

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
70

Total final enrolment
60

Key exclusion criteria
1. Pregnant or breastfeeding woman or woman planning pregnancy during the study
2. Subject deprived of rights by a court or administrative order
3. Major subject to a guardianship order
4. Subject residing in a health or social care establishment
5. Patient in an emergency setting
6. Subject with a skin disease in the test areas as well as skin allergy (particularly, e.g., acne, rosacea, eczema)
7. Volunteer presenting a stable or progressive serious disease (per investigator's assessment)
8. Immuno-compromised subject
9. Subject has hyperpigmentation skin symptoms
10. Subject with a history of allergy to cosmetic or personal care products or ingredients
11. Subject presenting excessive exposure to sunlight or UV radiation (investigator's assessment)
12. Subjects regularly practising aquatic or nautical sports
13. Subjects regularly attending a sauna
14. Subject with physical highly sensitive constitution
15. Subject with cardiovascular or circulatory history
16. Subject with a history of skin cancer or malignant melanoma
17. Subject with a history of medical beauty treatment and taking part in anti-aging studies in the last 3 months before the study
18. Intake of antihistamines, antibiotics, corticosteroids, non-steroidal anti-inflammatories or immune suppressants in the last 6 months before study

Date of first enrolment
08/12/2021

Date of final enrolment
12/12/2021

Locations

Countries of recruitment
China

Study participating centre
Shanghai China-Norm Quality Technical Service Co., Ltd
310, Building #13
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
Data is available on request from Li Jing (amy.li@loreal.com) or Liu Xingzuo (xingzuo.liu@loreal.com).
The type of data that will be shared: The shared data will include the average value of each attribute and the data summary.
Dates of availability: July 2025 following publication of the study in peer-reviewed journals.
Whether consent for data sharing was required and obtained from participants: The ICF that participants consented to and signed contained a section detailing their consent to the sharing of their photo and data for research purposes.
Comments on data anonymization: The subject information was semi-anonymized. We do not have access to subjects' full names; however, limited demographic data, such as age and skin type, were shared.
Any ethical or legal restrictions: There are no ethical or legal restrictions.
Any additional comments: No, there are no additional comments.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V4.0	16/11/2021	25/06/2025	No	No