

Effects of topical ectoine on skin responses to different laser treatments

Submission date 26/08/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/08/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/09/2026	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

Dr Izabela Załęska

ORCID ID

<https://orcid.org/0000-0001-9607-1345>

Contact details

Petrażyckiego 103 H
Cracow
Poland
30-399
+48 (0)504 265 052
izaleska@icloud.com

Additional identifiers

Study information

Scientific Title

Effects of topical ectoine compared with vehicle on cutaneous responses to different laser treatments in adults: a randomized within-participant controlled study

Study objectives

The primary objective of this study was to evaluate whether topical ectoine modifies cutaneous response and recovery following exposure to different laser modalities. The study assessed the effects of ectoine concentration, timing of application (preconditioning and/or post-treatment), and anatomical treatment site using randomized within-participant comparisons. Secondary objectives included the assessment of changes in skin barrier function, hydration, erythema, pigmentation, and ultrasound-derived skin parameters, as well as the evaluation of facial erythema following vascular laser treatment.

Ethics approval required

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Ethics approval(s)

Approved 12/12/2023, Bioethics Committee at the Regional Medical Chamber in Kraków (Ul. Krupnicza 11 A, Cracow, 31-123, Poland; +48 (0)601485237; bioetyka@oilkrakow.pl), ref: 227/KBL/OIL/2023

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Randomized within-participant (split-body) assignment

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Cutaneous response to laser exposure and subsequent skin recovery, including skin barrier function, hydration, erythema, pigmentation, and skin structural parameters, as well as facial erythema treated with vascular laser therapy

Interventions

Participants underwent controlled laser procedures at predefined anatomical sites using a randomized within-participant design. Different areas within the same participant were assigned to topical ectoine-containing formulations or a corresponding vehicle formulation without ectoine.

In the neck study component, one side of the neck was preconditioned with a topical formulation containing 7% ectoine applied twice daily before ablative Er:YAG laser treatment, while the contralateral side received the corresponding vehicle formulation.

Skin biophysical parameters were assessed at:

T0: before initiation of preconditioning (baseline)

T1: after completion of 7 or 14 days of preconditioning, immediately before Er: YAG treatment

T2: immediately after Er:YAG treatment

T3: 24 h after Er:YAG treatment

T4: 7 days after Er:YAG treatment

In the facial study component, both sides of the face underwent identical vascular Nd:YAG laser treatment. Following treatment, one side received a topical formulation containing 7% ectoine and the contralateral side received the corresponding vehicle formulation. The assigned formulations were applied twice daily throughout the study period. Participants underwent four laser treatment sessions at 7-day intervals.

Skin biophysical parameters were assessed at:

T0: before the first Nd:YAG treatment

T1: before the third treatment, after the first two therapeutic sessions

T2: 7 days after the fourth and final treatment

In the décolletage study component, predefined test fields were exposed to different laser modalities and compared across topical formulations containing different ectoine concentrations (1%, 5%, and 7%) and vehicle control. The protocol also evaluated different timing strategies, including ectoine preconditioning before laser exposure and post-treatment application.

Skin biophysical parameters were assessed at:

T0: before the start of the 7-day preconditioning period

T1: immediately after laser exposure

T2: 24 hours after exposure

T3: 14 days after exposure

Treatment allocation to anatomical sides or predefined test areas was randomized according to the respective study component. Cutaneous response and recovery were evaluated using standardized instrumental and imaging assessments at predefined time points.

Intervention Type

Mixed

Primary outcome(s)

1. Cutaneous response and recovery following laser exposure measured using instrumental assessment of skin barrier function and cutaneous response using transepidermal water loss (TEWL), corneometry, erythema index, USG and standardized skin imaging at baseline and predefined post-intervention follow-up timepoints according to each study component (see Interventions field for the full list)

Key secondary outcome(s)

Completion date

25/03/2024

Eligibility

Key inclusion criteria

1. Adults aged 29–65 years
2. Male and female participants
3. Fitzpatrick skin phototype II
4. Healthy skin in the anatomical areas selected for experimental laser exposure, where applicable
5. Presence of facial erythema suitable for vascular Nd:YAG laser treatment for participants included in the facial study component
6. Eligibility to undergo the laser procedures specified in the respective study component
7. Ability and willingness to comply with the study procedures, topical product application regimen, and scheduled follow-up assessments
8. Provision of written informed consent

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

29 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

90

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Active skin infection, inflammation, or other clinically significant skin disease in the treatment area
3. Open wounds or impaired skin integrity in the treatment area
4. Known hypersensitivity to any component of the study formulations
5. Contraindications to laser treatment
6. Use of systemic or topical medications known to significantly affect skin healing, inflammatory response, or photosensitivity during the relevant period before or during the study
7. Use of topical retinoids, hydroxy acids, chemical peels, vitamin C preparations, or other biologically active topical products in the treatment area during the study or within the specified washout period
8. Aesthetic, dermatological, or laser procedures in the study areas within the predefined period before enrollment or during the study
9. Excessive ultraviolet exposure or tanning of the treatment areas during the study period
10. Any medical condition considered by the investigator to interfere with safe participation, study assessments, or interpretation of the results

Date of first enrolment

08/01/2024

Date of final enrolment

15/01/2024

Locations

Countries of recruitment

Poland

Sponsor information

Organisation

CosmoMed

Funder(s)

Funder type

Funder Name

CosmoMed

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available