The impact of low level laser treatment on skeletal muscle and skin tissue mitochondrial respiration, metabolic activity and signaling in vivo in humans

Published: 04-03-2024
Last updated: 21-12-2024

Primary objective: To assess the impact of acute laser treatment on muscle tissue mitochondrial respiration in vivo in healthy, young adults. Secondary objective: To assess the impact of acute laser treatment on muscle cellular energy, anabolic,...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56671

Source
ToetsingOnline

Brief title
Laser Study

Condition

- Other condition

Synonym
muscle, skin

Health condition

Muscle and skin research (no disorders)

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Laser treatment, Mitochondria, Muscle, Skin

Outcome measures

Primary outcome

The primary outcome will be mitochondrial respiration of the LLLT treated and

non-treated leg based on muscle samples.

Secondary outcome

Secondary study parameters are muscle and skin gene expression, protein

signalling and enzyme activity.

Study description

Background summary

Low Level Laser Therapy (LLLT), also known as photobiomodulation, involves utilizing light, often from a low-power laser or LED ranging between 5mW and 500mW, to target a pathological area, aiming to stimulate tissue regeneration, alleviate inflammation, and provide pain relief. This technique has been utilized for over four decades to treat musculoskeletal, tissue healing and neurological issues. This light generally falls within the specific red or near-infrared (NIR) spectrum (600nm - 1000nm), and it boasts a power density of 1mW to 5W/cm2. Treatment usually entails exposing the affected region to the light for approximately a minute, repeated a few times weekly over several weeks. It's important to note that unlike other medical laser interventions, LLLT does not operate through ablation or thermal mechanisms; instead, it relies on a photochemical process similar to photosynthesis in plants, where light is absorbed and triggers a chemical transformation. Therefore, the laser light is absorbed by the skin without causing heat damage, allowing it to deeply penetrate tissues. Among the proposed effects are the stimulation of

mitochondrial respiration, enhancement of tissue oxygenation, and facilitation of tissue regeneration.
Current body of research shows the greatest positive effects of LLLT when used to treat cancer related oral mucositis and chronic pain. More recently LLLT has been suggested to be a potential therapy for controlling blood glucose levels, treat insulin resistance and support functional capacity outcomes in COPD patients. All these (potential) positive effects have underlying mechanisms that are not fully under stood.
LLLT has been shown to affect muscles after a single treatment. In rat models LLLT can reduce muscle fatigue, decrease muscle damage and inhibit inflammation processes. Similarly, LLLT showed increased muscle performance and improvements of muscle metabolic state when combined with exercise in an acute setting in humans. Interestingly, these acute effects have been proven when LLLT is applied more long-term, over several weeks, with improvements in muscle performance and damage. It has been suggested that the positive effects of LLLT on muscle tissue are based on changes in energy metabolism due to a stimulation of mitochondria, activation of muscle stem cells and favorable changes in muscle remodeling gene expression. However, there is no in vivo data in human on these underlying mechanism that can support muscle remodeling. Based on in vitro research, suggested effects on muscle mitochondria might be the most promising.
When muscle is stimulated by LLLT the skin undergoes LLLT at the same time. Therefore the skin is simultaneously a target for positive remodeling processes. It has been shown that LLLT can promote angiogenesis in the skin, increase signaling of anti-inflammatory proteins, increase collagen synthesis, support wound healing. Similarly to muscle, in vivo data to support these suggestions and their underlying mechanisms in human are lacking.
To design better therapies using LLLT for a variety of conditions it is important to understand the underlying mechanisms in a variety of tissues. Within our research group collection of muscle and skin samples is considered a standard procedure and both tissues are suggested to be affected by LLLT. Next to that, in combination with our experience in the assessment of mitochondrial respiration, gene expression, protein signaling and enzyme activity, we will be able to study the underlying mechanisms of LLLT on tissue remodeling.

Study objective

Primary objective: To assess the impact of acute laser treatment on muscle tissue mitochondrial respiration in vivo in healthy, young adults.

Secondary objective: To assess the impact of acute laser treatment on muscle cellular energy, anabolic, angiogenic and inflammatory pathways, along with enzyme activity.

Tertiary objectives: To assess the impact of acute laser treatment on skin cellular energy, anabolic, angiogenic and inflammatory pathways, along with

enzyme activity.

Study design

The present study utilizes an acute within-subject design in healthy young adult participants. In total, 12 healthy young adults (6 men and 6 women) will participate in the study. Participants* legs will be randomly assigned to low level laser treatment or no treatment (Figure 1). Each participant will participate in a screening session (~1 h) and 1 experimental test day (~1.5 h).

Intervention

One leg of the subjects will receive LLLT, while the other leg will receive no treatment. After the treatment muscle and skin biopsy samples will be taken from both legs.

Study burden and risks

The risks involved in participating in this experiment are minimal. LLLT has been shown to have no side effects and induce no harm. Muscle and skin biopsies will be obtained under local anesthesia by an experienced physician. The muscle biopsy may cause some minor discomfort, which is comparable to muscle soreness or the pain one has after bumping into the corner of a table. Participants will visit the University two times. The first visit will involve a screening visit (1 h), during which the eligibility of the participant will be assessed and the informed written consent will be obtained. For the second visit (experimental trial, 1.5 h) participants are required to come to the University in a fasted state, not having consumed any food or beverages (except for water) as from 22:00 the evening before. Also, 2 days prior to the experimental trial participants need to record their food intake and activities performed. During these 2 days participants are not allowed to perform heavy physical exercise or drink alcohol. Filling out the food and activity log properly will take the participant about 30 min each day. There is no direct benefit for the participants, except from their contribution to scientific knowledge.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Male or female sex
• Aged between 18 and 35 y inclusive
• BMI between 18.5 and 30 kg/m2

Exclusion criteria

• Participating in a structured (progressive) exercise program or >4h of vigorous physical activity per week.
• Smoking regularly (i.e. >5 cigarettes/week)
• Pregnancy
• Hormonal replacement therapy
• Diagnosed musculoskeletal disorders
• Diagnosed metabolic disorders (e.g. diabetes)
• Diagnosed skin disorders
• Use of any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories).
• Chronic use of anti-coagulants

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-06-2024
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	K-Laser Cube Plus 30
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-03-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85367.068.24