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Using light therapy at home to improve dental hygiene: a study on healthy adults

Submission date
13/03/2025

Recruitment status
No longer recruiting

Registration date
28/03/2025

Overall study status
Completed

Last Edited
14/03/2025

Condition category
Oral Health

[ ] 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
Toothbrushing, whether with an electric or manual toothbrush, often leaves 35–50% of plaque behind. Regular use of antibacterial photodynamic therapy has emerged as a promising method to enhance oral hygiene at home. This study aims to evaluate the effectiveness of the antibacterial Lumoral® light-activated treatment in reducing dental plaque as part of daily dental care in healthy volunteers.

Who can participate?
Healthy adults who do not have fixed orthodontic appliances, fixed partial dentures, advanced periodontitis, significant pathology in the oral cavity, or restorable caries lesions. Participants should not have used antibiotics within the last month, should not smoke, and should not have had recent professional dental cleaning or participated in other oral health examinations.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive oral hygiene instructions and use Lumoral® as an additional plaque control method twice a week. The other group will receive oral hygiene instructions alone. Dental plaque will be measured at the start and after four weeks using the Rustogi-modified Navy Plaque Index. Researchers who do not know which group participants are in will conduct the measurements.

What are the possible benefits and risks of participating?
Participants may benefit from improved dental hygiene and reduced plaque levels. Risks are minimal but may include mild discomfort from using the Lumoral® device.

Where is the study run from?
Koite Health Ltd. (Finland)

When is the study starting and how long is it expected to run for?
August 2022 to March 2023

Who is funding the study?
The study was performed in collaboration with the Metropolia University of Applied Sciences

and Koite Health Ltd.
Koite Health Ltd. provided the investigational devices for the study. No direct financial contributions to the researchers or the study center were made.

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Regularly home-applied dual-light photodynamic therapy on dental hygiene- a prospective randomized study in healthy adults

Acronym
SHINE

Study objectives
The Lumoral® treatment, when used twice a week as an adjunct to regular oral care, improves oral hygiene in healthy individuals.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/01/2023, The Human Sciences Ethics Committee of the Helsinki Region Universities of Applied Sciences (Myllypurontie 1, Helsinki, 00920, Finland; +358 401937758; eettinen.toimikunta@metropolia.fi), ref: § 8/2023

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental plaque

Interventions
At baseline and at 4-week follow-up (+/- 1 week), the biofilm of the subjects' mouths is stained using plaque dye, and clinical plaque index measurements is obtained.

After the baseline visit, study subjects are given comprehensive oral self-care instructions including mechanical biofilm removal from free tooth surfaces and interdental spaces.

Those randomized in the Treatment group are given a Lumoral® Treatment device and thorough verbal and written instructions to perform dual-light aPDT at home in addition to the comprehensive oral self-care instructions.

The participants are randomly assigned to the test and control groups using a sealed envelope technique.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lumoral

Primary outcome measure
Dental plaque levels measured using the Rustogi-modified Navy Plaque Index from clinical plaque staining and scoring at Baseline and Week 4 (+/-1 week)

Secondary outcome measures
Subjective experience of using the Lumoral® Treatment device measured using a structured questionnaire at Week 4 (+/-1 week)

Overall study start date
26/08/2022

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Subjects had to be from 18 to 70 years' age and good general health assessed by study participants themselves.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Oral health-related issues, including fixed orthodontic appliances, fixed partial dentures, advanced periodontitis, significant pathology in the oral cavity, or restorable caries lesions.
2. Medication-related issues, including use of antibiotics within one month.
3. Other factors, including smoking, participation in other oral health examinations, and recent professional dental cleaning.

Date of first enrolment
15/02/2023

Date of final enrolment
03/03/2023

Locations

Countries of recruitment
Finland

Study participating centre
Metropolia University of Applied Sciences, Myllypuro Campus
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Sponsor information

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Koite Health Ltd.

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Koite Health Ltd.

Results and Publications

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

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
No plan to share IPD.

IPD sharing plan summary

Not expected to be made available