ISRCTN83029100 https://doi.org/10.1186/ISRCTN83029100

The effectiveness of regular home use of photodynamic therapy for controlling oral plaque in healthy adults

Submission date 13/03/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/03/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/03/2025	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental plaque is a leading cause of oral health problems, including cavities and gum disease. While regular toothbrushing and flossing are essential for maintaining good oral hygiene, they may not remove all plaque effectively. This study aimed to evaluate whether the Lumoral® antibacterial photodynamic therapy (a type of light-based treatment) can help improve oral hygiene when used alongside regular brushing and flossing.

Who can participate?
The study was open to healthy adults aged 18–40 years who had good oral hygiene habits, no significant dental issues (such as gum disease or active tooth decay), and minimal tartar buildup. People with certain medical conditions, those taking regular medications (except oral contraceptives), and pregnant or breastfeeding women were not eligible to take part.

What does the study involve?
This study followed a crossover design, meaning each participant experienced both the test treatment (using Lumoral®) and the standard treatment (regular brushing and flossing). The study lasted 6 weeks and included three phases:
1. 2 weeks using the Lumoral® device.
2. 2-week crossover phase.
3. 2 weeks with standard oral hygiene only.
Plaque levels were measured at four timepoints using clinical photographs and bacterial samples collected from the gumline.

What are the possible benefits and risks of participating?
Potential benefits: Participants might experience improved oral hygiene and reduced plaque levels, potentially lowering the risk of gum disease and cavities.
Possible risks: The Lumoral® treatment involves exposure to light with a marker substance. The device produces heat as part of the treatment process. While no serious risks were expected, some participants might find the heat and increased saliva secretion during the treatment a little uncomfortable.

Where is the study run from?
Institute of Dentistry, University of Tartu (Estonia)

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

Who is funding the study?
The study was performed in collaboration with the Institute of Dentistry, University of Tartu and Koite Health Ltd.
Koite Health Ltd. provided the investigational devices and will pay for the bacterial sample analysis. No direct financial contributions to the researchers or the study center were made.

Who is the main contact?
Mr Mikko Kylmänen, mikko.kylmanen@koitehealth.com

Contact information

Type(s)
Scientific

Contact name
Dr Tommi Pätilä

ORCID ID
https://orcid.org/0000-0003-2219-4689

Contact details
Stenbäckinkatu 9
Helsinki
Finland
00290
+358 (0)440130770
tommi.patila@gmail.com

Type(s)
Public

Contact name
Mr Mikko Kylmänen

Contact details
Karaportti 5
Espoo
Finland
02610
+358 (0)407245934
mikko.kylmanen@koitehealth.com

Type(s)
Principal investigator

Contact name
Prof Riina Runnel

Contact details
University of Tartu
Faculty of Medicine
Institute of Dentistry
Puusepa 1a
Tartu
Estonia
50406
+372 (0)77319856
riina.runnel@ute.ee

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of regular home use of photodynamic therapy for controlling oral plaque in healthy adults

Acronym
FAST

Study objectives
Daily Lumoral® use improves oral hygiene in healthy individuals when used as an adjunct to oral self-care

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2024, Research Ethics Committee of the University of Tartu (UT REC) (Raekoja Plats 9, Tartu, 51004, Estonia; +372 (0)77376215; eetikakomitee@ut.ee), ref: 385/T-21

Study design
Prospective randomized cross-over trial

Primary study design

Interventional

Study type(s)
Prevention, Treatment

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

Interventions
The study is conducted at the University of Tartu, Institute of Dentistry (Tartu, Estonia) as part of dental students' academic research. All participants provided written informed consent prior to enrollment. The study follows a crossover design with two groups (1 and 2) over 6 weeks, consisting of three phases: 2 weeks of study device use, a 2-week cross-over phase, and 2 weeks of standard treatment. Measurements are taken at four timepoints: Baseline 1, after 2 weeks, Baseline 2, and again after 2 weeks. At each timepoint, clinical photographs of six index teeth are taken, plaque levels are assessed using the Green-Vermilion index, and bacterial samples are collected from the gingival sulcus/enamel-cementum border using a paper pin at four sampling sites.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Plaque levels measured using the Green-Vermilion Plaque Score from clinical photographs taken at Visit 1 (Week 0), Visit 2 (Week 2), Visit 3 (Week 4), and Visit 4 (Week 6).

Key secondary outcome(s))
Bacterial composition in the gingival sulcus measured using 16S PCR analysis of bacterial samples collected from the gingival pocket at Visit 1 (Week 0), Visit 2 (Week 2), Visit 3 (Week 4), and Visit 4 (Week 6)

Completion date
22/04/2024

Eligibility

Key inclusion criteria
1. Good oral hygiene, as evidenced by a subjective report of brushing their teeth twice a day and flossing daily
2. No comorbidities
3. Minimal supragingival calculus in the lower front

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Concomitant disease
2. Daily mouthwash use (chlorhexidine 0.12% or 0.2%)
3. Gum disease (gingivitis or periodontitis)
4. Candidiasis
5. Daily treatment with medication other than oral contraceptives
6. Presence of subgingival calculus
7. Active caries on the buccal, lingual, or occlusal surface
8. Non-student status
9. Pregnancy
10. Breastfeeding

Date of first enrolment
18/02/2024

Date of final enrolment
24/03/2024

Locations

Countries of recruitment
Estonia

Study participating centre
University of Tartu, Institute of Dentistry
L. Puusepa 1a
Tartu
Estonia
50406

Sponsor information

Organisation
Koite Health Oy

Funder(s)

Funder type
Industry

Funder Name
Koite Health Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The participant-level data will not be made available due to privacy regulations and ethical considerations. The dataset is pseudonymized and it contains sensitive health information, and sharing it publicly could compromise participant confidentiality. The original data will be securely stored in accordance with institutional and national (Estonian) data protection policies at the University of Tartu. The digitalized, shared data will be stored by Koite Health Ltd in accordance with the national (Finnish) data protection policies. The data will only be accessible to authorized researchers under the appropriate data governance procedures of both countries.

IPD sharing plan summary
Not expected to be made available