Divergent Low Level Laser Therapy as novel treatment for oral mucositis in patients with oral or oropharyngeal squamous cell carcinoma’

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The use of dLLLT will lower the severity of mucositis in patients with oral or oropharyngeal squamous cell carcinoma during radiotherapy

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21094

Bron
NTR

Verkorte titel
Laser I

Aandoening

Oral mucositis in oral or oropharyngeal squamous cell carcinoma

Ondersteuning

Primaire sponsor: Stichting Overleven
Overige ondersteuning: Stichting Overleven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Radiotherapy (RT) is one of the most effective modalities for the treatment of head and neck cancers (HNC). Oral mucositis (OM) is one of the potentially severe side ef-fects of RT. Patients suffering from OM experience pain, swallowing problems, use of anal-gesics, and decreased oral intake. The quality of life is severely decreased and patients are more vulnerable for infections due to OM. Moreover, the (supportive) care for patients with OM has a considerable economic impact. Currently at the University Medical Center (UMC) Utrecht, the therapy for OM has a supportive character and consists of analgesics for pain management, mouth rinses and good oral hygiene for reducing infectious risk, and nutritional support for the decreased oral intake. Low Level Laser Therapy (LLLT) might be the most feasible in patients with HNC and thus is subject of this study. At present time, however, LLLT requires expensive equipment and specialized training. Current LLLT is spot-focused and thus named convergent Low Level Laser Technology. One lesion in the oral cavity can be treated at a time during a few seconds. Though, we have the availability to use a laser device, the Mellinn650, which is not expensive, can be applied by the patient and does not require much training. This is because it uses divergent Low Level Laser Technology (dLLLT), which does not work specifically on one spot in the oral cavity, as with classic LLLT devices, but will treat the complete oral cavity at the same time with the use of two clips emitting laser light simultaneously.
Objective: The main aim of this study is to get insight in the effectiveness of dLLLT added to usual care (UC) compared to UC in patients with oral or oropharyngeal squamous cell carcinoma (O/OPSCC) during RT on the severity of OM. The second aim of this study is to get insight in the effectiveness of dLLLT added to UC compared to UC in patients with O/OPSCC during RT in the number of days with OM, the number of oral infections, pain, xerostomia (dry mouth), maximum mouth opening, taste, and quality of life. The third aim of this study is to get insight in the perception of patients with O/OPSCC related to dLLLT added to UC and UC only.
Study design: This study is a randomised clinical trial and will take place at UMC Utrecht . In total 70 patients will be included; 35 will get UC and dLLLT (intervention group) and 35 will get UC (control group).
Study population: All patients with primary O/OPSCC scheduled for RT at UMC Utrecht.
Intervention: The Mellinn650 is a semiconductor laser treatment instrument, capable of providing dLLLT. The light spots are situated in the 2 disposable mouth clips and emit laser light with a wavelength of 650 nanometers (nm) and an adjustable output power of 1-5 milli-watts (mW) in both clips (total maximum power of 10 mW). The Mellinn650 is not spot-focussed, thus irradiating the entire interior of the mouth, the so-called divergent Low Level Laser Therapy (dLLLT). The time of therapy is 2 times per day 30 minutes and will be used during the RT period of 7 to 8 weeks.
Main study parameters/endpoints: The severity of OM will be measured by the WHO-criteria

and National Cancer Institute’s Common Toxicity Criteria (NCI-CTC).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The measurement sessions at week 1, 4, 8, and at 6 months will take maximally 40 minutes. The measurement sessions at week 2, 3, 5, 6, 7 will take 10 minutes.
The burden is in our opinion minimal. There are no specific advantages or risks for the subjects in this study, because the physical burden is minimal and so the consequences for the subjects are nihil.

Doel van het onderzoek

The use of dLLLT will lower the severity of mucositis in patients with oral or oropharyngeal squamous cell carcinoma during radiotherapy

Onderzoeksopzet

Week 0 (M0), 2 (M2), 3 (M3), 4 (m4), 5 (M5), 6 (M6), 7 (M7), 8 (M8), and at 6 months (M9).

Onderzoeksproduct en/of interventie

Divergent low level laser therapy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Subjects should have a primary O/OPSCC
• Subjects who are scheduled for RT
• Subjects who are competent
• Subjects should be aged 18 years or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• O/OPSCC recurrence after primary O/OPSCC treatment
• Unable to read Dutch
• Unable to complete the questionnaires

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-09-2019
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7862
CCMO	NL69879.041.19

Resultaten