Divergent Low Level Laser Therapy as novel treatment for oral mucositis in pediatric cancer patients

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What is the effect of divergent LLLT on the number of days of mucositis > grade 1?

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24457

Bron
Nationaal Trial Register

Verkorte titel
DuLaMP

Aandoening

Children, Cancer, Oral Mucositis, Low Level Laser Therapy.

Kinderen, kanker, orale mucositis

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), Beatrix Children's Hospital
Overige ondersteuning: Mellinn BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of days of mucositis > grade 1

Toelichting onderzoek

Achtergrond van het onderzoek

Oral mucositis (OM) is one of the potentially severe side effects of chemotherapy and radiotherapy, and can lead to severe pain, suboptimal feeding, increased risk of infection and a reduced quality of life. Several therapies have been suggested for OM, however until now no treatment for OM in children is proven effective. Recent evidence supports Low Level Laser Therapy (LLLT) as possible prophylaxis or treatment of OM. Since OM happens often in children receiving high dose chemotherapy it would be interesting to know the effects of LLLT in children suffering from OM. In this study we will use a new laser device, the Mellinn650, which is not expensive and does not require much training, because it uses divergent Low Level Laser Technology (dLLLT). This dLLLT is easy to use and seems therefore very practical for use in the pediatric oncology department. No information is available about therapeutic use of
dLLLT in children. Therefore we will study the effect of therapeutic use of dLLLT in pediatric patients suffering from chemotherapy-induced OM on the number of days suffering from mucositis, in a double-blind randomized placebo-controlled trial.
Study population: Children (4-18 yrs of age) admitted with chemotherapy-induced mucositis to one of the participating centers.
Intervention: Divergent Low Level Laser Therapy using the Mellinn650.
Main study parameters/endpoints: Days of mucositis > grade 1

Doel van het onderzoek

What is the effect of divergent LLLT on the number of days of mucositis > grade 1?

Onderzoeksopzet

During admission, the following items will be registered:

- Severity of mucositis, scored using the NCI-CTCAE scoring system (daily);

- Side effects of treatment (when occurring);

- Pain, scored depending on age using the VAS or Faces scoring system (twice daily);

- Pain medication (when administered);

- Infectious complications (when occurring);

Five days after the start of study treatment, the patient will fill in a questionnaire to

measure his or her quality of life. After the patient is discharged, the duration of hospital stay in days and the number of bacteraemias will be looked up in the electronic patient record by one of the researchers. In addition, the researcher will calculate the costs of the admission.

Onderzoeksproduct en/of interventie

Shorty after diagnosis of the patient, at least 14 days before mucositis possibly occurs, the investigator will inform the patient and / or the parents/caretakers about this study with oral and written information on the kind of study, duration and possible risks. The patient will then be
included. After chemotherapy courses possibly causing mucositis (primarily ALL MTX courses, T-NHL MTX courses, COPAD/COPADM courses, Osteosarcoma all courses, after SCT), the parents / child will fill in the diary on a daily basis to study the incidence of mucositis. (ChIMES)

Once the patient is admitted to the hospital with > grade 1 oral mucositis, he / she will be randomized for dLLLT or placebo. The local researcher will initiate the allocated treatment which will start on day of admission.
Patients will be given either divergent Low Level Laser Therapy (dLLLT) or Placebo Therapy (PT). For both treatments the Mellinn650 will be used as intraoral device. For dLLLT the Mellinn650 will be used with 2 clips with laser light. For PT the Mellinn650 will be used with 2 clips that do not emit light.
Treatment times: 4 times a day during 30-60 minutes.

Contactpersonen

Publiek

Pediatric Oncologist and Hematologist
Hanzeplein 1
W.J.E. Tissing
Groningen 9713 GZ
The Netherlands
+31 (0)50 3614213

Wetenschappelijk

Pediatric Oncologist and Hematologist
Hanzeplein 1
W.J.E. Tissing
Groningen 9713 GZ
The Netherlands

+31 (0)50 3614213

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 4-18 years (below the age of 4 years the device is not feasible due to the size of the clips).

Written informed consent

Diagnosed with a haematological malignancy or solid tumor, or scheduled for hematopoietic stem cell transplantation.

Treatment with chemotherapy possibly causing oral mucositis.

Patients will only be randomized to receive either dLLLT or Placebo Therayp (PT) if they meet all of the
following criteria:

- Chemotherapy-induced oral mucositis > grade 1

- Hospitalized

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous participation

- Impossibility to use dLLLT or PT (e.g. mechanical ventilation)

- Patients and their parents are excluded when they are insufficiently capable of speaking and understanding the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2016
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-01-2016
Soort:	Eerste indiening

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	NL5539

Register	ID
NTR-old	NTR5659
Ander register	: METC 2015/081

Resultaten