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

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Primary Objective: - To assess the effect of divergent LLLT on the number of days of mucositis > grade 1Secondary Objective(s): - To assess the effect of divergent LLLT on the severity of mucositis - To assess the effect of divergent LLLT on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Oral soft tissue conditions
Study type	Interventional

Summary

ID

NL-OMON50231

Source
ToetsingOnline

Brief title
DuLaMP

Condition

- Oral soft tissue conditions

Synonym
Oral mucositis; damage of oral mucosa

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Mellinn bv

Intervention

Keyword: Cancer, Low Level Laser Therapy, Oral Mucositis, Pediatrics

Outcome measures

Primary outcome

Number of days of mucositis > grade 1

Secondary outcome

i. Peak level of mucositis according to the NCI-CTCAE scoring system

ii. Peak level of mucositis according to the WHO mucositis system

iii. Days of oral pain, measured with VAS or Faces scoring system (age dependent)

iv. Peak level of pain, measured with VAS or Faces scoring system (age dependent)

v. Use of pain medication;

1. Type and dosage of medicine;

2. Length of use in days;

3. Frequency.

vi. Number of infectious complications during hospital stay

vii. Quality of life, measured with the Pedsqual questionnaire five days after the start of study treatment

viii. Nutritional state (length at start, daily weight)

ix. Positive culture not otherwise specified (e.g. throat culture, wound culture)

x. Costs

xi. Incidence of oral mucositis, according to the Child International

Mucositis

Evaluation Score (ChIMES)

Study description

Background summary

The survival of children with cancer increased extensively in the last decades due to more intensive treatment protocols consisting of chemotherapy, radiotherapy and surgery. Unfortunately, these intensive treatments potentially cause severe treatment related side effects. Oral mucositis (OM) is one of these 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. We will study the effect of therapeutic use of divergent Low Level Laser Therapy(dLLLT) in pediatric patients suffering from chemotherapy-induced OM in a double-blind randomized placebo-controlled trial.

Study objective

Primary Objective:
- To assess the effect of divergent LLLT on the number of days of mucositis > grade 1

Secondary Objective(s):
- To assess the effect of divergent LLLT on the severity of mucositis
- To assess the effect of divergent LLLT on the number of infections
- To assess the effect of divergent LLLT on the quality of life
- To assess the incidence of mucositisin children treated with cancer

Study design

Double-blind randomized placebo controlled trial

Intervention

Patients will be given either divergent Low Level Laser Therapy (dLLLT) or placebo therapy(PT).) For both treatments the Mellinn650 will be used. For dLLLT the Mellinn650 will be used with clips with laser light (laser and prism situated in the clips). For PT the Mellinn650 will be used with clips that do not emit light (laser is internally disconnected).

Study burden and risks

Included patients will either receive dLLLT or placebo therapy (PT). All pediatric patients with cancer therapy induced oral mucositis will benefit from this study in the future, since the results, either positive or negative, of this study will be implemented in the clinic after the study is finished. The burden of the patient is minimal, since no extra diagnostic procedures will be done and dLLLT therapy is non-invasive. The patient has to fill in a diary daily. And the patient has to fill in a quality of life questionnaire ones.
LLLT has no reported or theoretical serious adverse effects or side effects beyond those reported for PT. Therefore there are no risks associated with the study other than the risks the study patients already have due to their illness and therapy, thus being prone to severe infections.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Age 4-18 years (below the age of 4 the device is not feasible due to the size of the clips).
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 if they meet all of the following criteria:
- Cancer therapy induced oral mucositis > grade 1
- Hospitalized
- Written informed consent

Exclusion criteria

- Previous participation
- Impossibility to use dLLLT or PLT (e.g. mechanical ventilation)
- Patients and their parents are excluded when they are insufficiently capable of speaking and understanding the Dutch language

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2016

Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Divergent low level laser therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-01-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-01-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-06-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50630.042.15