LI-TASTE study: Light for taste

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Assess the efficacy of PBMT to prevent/ameliorate dysgeusia in patients with multiple myeloma treated in Amsterdam UMC with conditioning chemo(radio)therapy followed by autologous stem-cell-transplantation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56295

Source
ToetsingOnline

Brief title
LI-TASTE study

Condition

- Other condition
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
dysgeusia, taste changes

Health condition

mond aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,THOR

Photomedicine,TKI subsidie

Intervention

Keyword: dysgeusia, light therapy, stemcell transplant, taste changes

Outcome measures

Primary outcome

Objective taste function

Secondary outcome

Subjective taste function

Presence and severity of hyposalivation

Presence and severity of xerostomia

Patient reported oral mucositis

Global and oral health-related QoL

Patient reported oral health

Caloric/dietary intake

Study description

Background summary

In 2020, 115,000 Dutch patients were diagnosed with cancer. Up to 85% of patients treated with radiotherapy involving the head and neck, chemotherapy or stem-cell-transplantation (SCT) suffer from taste disorders (dysgeusia). Dysgeusia is one of the most distressing adverse effects of cancer therapy, may be long-lasting and may contribute to malnutrition and decreased QoL. Dysgeusia pathobiology is complex and relates to direct damage to taste buds by anticancer therapies, neuropathy and/or mucosal infection and inflammation. Hyposalivation and concurrent medications may also play a role as well as smoking and poor oral health. Zinc suppletion, clonazepam and delta-9-tetrahydrocannabionol have only limited success. Thus, dysgeusia in cancer patients represents a significant unmet clinical need. Photobiomodulation therapy (PBMT) using specific wavelengths of

red/near-infrared light reduces oxidative stress and increases ATP in cells, which improves cell metabolism and reduces inflammation. PBMT is safe and effective for the prevention of oral mucositis and is linked to pain reduction, nerve damage recovery and improved wound healing. There is emerging evidence for PBMT to improve taste, likely based on its regenerative effects on taste buds and nerves involved in taste function. However, there is need for more reliable data on the effect of PBMT on taste.

Study objective

Assess the efficacy of PBMT to prevent/ameliorate dysgeusia in patients with multiple myeloma treated in Amsterdam UMC with conditioning chemo(radio)therapy followed by autologous stem-cell-transplantation.

Study design

Phase 2, single centre, prospective, longitudinal, double-blinded, randomized, controlled study.

Intervention

Patients will be blinded to receive either PBMT or sham-PBMT.

Study burden and risks

Patients will be seen at the same time that they have a regular appointment in the hospital. The patient reported outcomes are also filled out at several time points during hospitalization. No invasive procedures are performed. The intervention comes with no risks. Possible less taste complications after treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with multiple myeloma; 18 years of age receiving HDM followed by SCT

Exclusion criteria

Having taste disorders not related to SCT (e.g. COVID-19)
History of a head and neck tumor treated with surgery and/or (chemo)radiation
Neurological diseases (e.g. Parkinson*s disease)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2024
Enrollment:	52
Type:	Actual

Medical products/devices used

Generic name:	THOR Oral Pro
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	14-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84772.018.23