TSDIST study: Taste and smell disturbances in graft versus host disease patients

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Primary objective: To study the prevalence and nature of taste and smell disturbances in GvHD patients. Secondary objective: To study whether the prevalence and nature of taste and smell disturbances are related to - oral GvHD - salivary flow - oral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48338

Source
ToetsingOnline

Brief title
TSDIST study

Condition

- Other condition
- Leukaemias

Synonym
smell changes, taste changes

Health condition

smaak-en reukstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: graft versus host disease, oral cavity, smell, taste

Outcome measures

Primary outcome

- Qualitative and quantitative measurements of taste disturbances -

Quantitative measurements of smell disturbances

Secondary outcome

- Amount of (un)stimulated salivary flow - (Oral health related) quality of

life - Score overall GvHD - Oral GvHD (subjective/objective) - Perception of

taste and smell changes

Study description

Background summary

Over the past 50 years, more than a million hematopoietic stem cell transplantations (HSCT) have been performed. The success of allogeneic HSCT is tempered by one of the most common and potentially life-threatening complications, graft-versus-host disease (GvHD), an alloimmune response of donor immune cells against healthy recipient\u2019s tissues including skin, liver, lungs, gut, oropharynx and oral cavity. Despite improvements in donor selection, tailored conditioning regimens, and better supportive care, the incidence of GVHD will increase related to more frequent use of unrelated donors and the aging of the donor and de recipients. Clinical oral complications of GvHD manifest from relatively innocent oral lichen planus-like erythema/ulcers up to severe oral lesions, salivary dysfunction, impaired mouth opening and taste disturbances. A limited number of studies have focused on taste alterations among HSCT patients. Alterations in taste perception are commonly caused by upper respiratory viral infections and infections in the oral cavity. Furthermore, activation of inflammatory pathways by immune

dysregulation may alter taste bud homeostasis and contribute to the development of taste disorders. Finally, treatment modalities such as radiotherapy and chemotherapy can also temporarily or permanently disrupt taste bud homeostasis through direct damage to the taste cells. Although there is some evidence for taste changes in allogeneic HSCT recipients, it is not clear what the prevalence of taste and smell changes is and whether these changes are related to oral GvHD. Therefore, the aim of this project is to study the prevalence of taste and smell disturbances in GvHD patients and to study whether there is a relationship between post-allogeneic HSCT taste and smell disturbances and oral GvHD.

Study objective

Primary objective: To study the prevalence and nature of taste and smell disturbances in GvHD patients. Secondary objective: To study whether the prevalence and nature of taste and smell disturbances are related to - oral GvHD - salivary flow - oral health related quality of life - subjective complaints of taste and smell disturbances

Study design

Single center, cross-sectional study that takes place at the departments of hematology and oral and maxillofacial surgery in the AMC. All patients are diagnosed with GvHD, we will compare two subgroups: with and without oral GvHD. The duration of the study will be approximately 1 year.

Study burden and risks

No risk for participants

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

adult allogeneic hematopoietic stem cell transplantation recipients with graft versus host disease

Exclusion criteria

allogeneic HSCT recipients without GVHD, patients with neurodegenerative diseases and smokers

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2019

Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2019
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	NL69437.018.19