Long-term oral complications in patients treated with hematopoietic stem cell transplantation

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26439

Source
NTR

Brief title
HOME2

Health condition

Dental and oral diseases

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Outcomes are assessed once during study visit.
Periodontal disease: full pocket depth index will be registered at six surfaces of each tooth. Bleeding on probing will be noted (Y/N) for each surface. The percentage of bleeding on

probing will be reported. Gingival recession will be registered for two surfaces (buccal and lingual) on each tooth as the distance between gingival margin and cemento-enamel junction. Furcation accessibility of (pre)molars will be noted, as well as tooth mobility of all teeth.
Dental caries: the ICDAS-II will be used to qualitatively asses caries. All tooth surfaces will be scored and scores ≥2 will be listed:
2: distinct visual change in enamel
3: localized enamel breakdown (without clinical visual signs of dental involvement)
4: underlying dark shadow from dentin
5: distinct cavity with visible dentin
6: extensive distinct cavity with visible dentin
Root caries
7: discoloration but no cavitation
8: discoloration with cavitation
Caries history and necessary treatments due to caries in the past 10 years will be assessed with the help of general dentists' charts including radiographs.

Secondary outcome

Outcomes are assessed once during study visit.
Tooth loss: the number of teeth present at the 5 years dental check-up will be measured. General dentists' charts including intra- and extraoral radiographs will be used to evaluate the reasons for extractions in the past 10 years.
Oral mucosal cGVHD: oral mucosa will be inspected for oral alterations. The NIH oral cGVHD Activity Assessment will be used to assess oral cGVHD.
Unstimulated and stimulated salivary flowrate and pH: patients will be asked to refrain from eating or drinking 1 hour before the collection. To collect unstimulated whole saliva, patients will be asked to spit the saliva in a preweighed plastic cup for 5 min without making any effort to increase the salivary flow. During the collection of stimulated whole saliva, patients will chew on a piece of neutral chewing gum base. After collection, samples will be weighted and flow rates estimated by assuming 1 gram of saliva equals 1 mL. The pH will be determined using pH indicator strips (pH-indicator strips 5.5 – 8.0, Hydrion, New York).
Maximum mouth opening: maximum mouth opening is measured as the greatest distance between incisal edge of maxillary central incisor to the incisal edge of mandibular central incisor, when the mouth is opened as wide as possible. The patient will be asked to open as wide as possible three times. During the third attempt the interincisal distance will be measured.
Oral microbiome: patients will be asked to rinse during 10 seconds with a sterile 0,9% saline solution. The rinses will be collected into sterile tubes, spun down, resuspended in sterile PBS and frozen at -80°C within 2 hours.
Oral health-related quality of life and xerostomia: patients will be asked to fill in the EORTC OH-17 questionnaire.
Masticatory function: patients will be asked to fill in the MFIQ questionnaire.

Study description

Background summary

Rationale: the oral cavity is a common site for complications related to hematopoietic stem cell transplantation (HSCT). The previously performed multicenter study “Oral Complications in patients treated with hematopoietic stem cell transplantation” with the acronym Orastem/HOME(performed in RADBOUD UMC and AMSTERDAM UMC, NL52117.018.15 studynumber 2015_087) focused on oral complications up to 18 months after HSCT. However, there is a need for long-term follow-up of HSCT recipients to evaluate the development of periodontal disease and dental caries. The knowledge on long-term oral complications andtheir risk indicators, clinical characteristics, and consequences is inadequate. The present observational study with the acronym ‘HOME2’ will be performed to attenuate this gap of knowledge. We anticipate that the results of ‘HOME2’ will provide a scientific base for the development of individualized preventive strategies.
Objective: to describe the long-term oral complications after HSCT, and evaluate periodontal changes and caries progression in HSCT recipients five years after transplantation.
Study design: one additional follow-up visit to the prospective observational Orastem/HOME study.
Study population: HSCT survivors who were included in the previously performed Orastem/H-OME study (patients ≥ 18 years diagnosed with a malignancy who received full or reduced intensity conditioning therapy followed by autologous or allogeneic HSCT between 2015 and 2018).
Main study parameters/endpoints: periodontal changes and caries progression five years post-HSCT.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: the burden for patients of this observational study is mild. Patients are asked to visit the site once, which is located next to the hospital where the recipients visit their doctor for regular check-ups. During the site visit, the study procedure includes an oral examination, measuring salivary flow rate and pH and completion of questionnaires. There are no direct risks or benefits for participating subjects in this study. The anticipated knowledge gained from this study will help to improve future supportive care protocols for HSCT recipients.

Study objective

HSCT recipients are at risk for developing oral complications five years after transplantation.

Study design

One

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Member of the closed cohort of the Orastem/H-OME study
- Able and willing to provide written and dated informed consent prior to any study specific procedure

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients who received a second autologous or allogeneic HSCT
- Patients unable to give written and dated informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-11-2021
Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9825
Other	CMO : 2021-12963

Study results