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

Gepubliceerd: 21-10-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26439

Bron
NTR

Verkorte titel
HOME2

Aandoening

Dental and oral diseases

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One

Contactpersonen

Publiek

Radboudumc Dentistry
Lucky van Gennip

0243614027

Wetenschappelijk

Radboudumc Dentistry
Lucky van Gennip

0243614027

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	25-11-2021
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9825
Ander register	CMO : 2021-12963

Resultaten