Oral complications of hematopoietic stem cell transplantation

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The oral environment (e.g., the oral microbiome and salivary proteome) contributes to the risk and severity of developing oral and dental complications (e.g., oral mucositis and oral graft versus host disease and dental diseases)

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23941

Bron
Nationaal Trial Register

Verkorte titel
ORA-STEM/H-OME study

Aandoening

hematopoietic stem cell transplantation, mucositis, graft versus host disease, caries, periodontitis

stamceltransplantatie, mucositis, graft versus host ziekte, mondgezondheid

Ondersteuning

Primaire sponsor: Academic Center for Dentistry Amsterdam (ACTA)
Academic Medical Center Amsterdam (AMC)
Radboud Universitair Medisch Centrum, Nijmegen
Carolina's Medical Center, Charlotte,NC, USA
Sahlgrenska University Hospital Gothenburg, Sweden

Overige ondersteuning: Dutch H-OME study: Koninklijk Wilhemina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence, severity and temporal relationship of oral complications and their relationship with the type of conditioning regimen by using questionnaaires and physical examination
 Composition of the oral microbiome, salivary output and proteome before, during and after transplant and assessment of any associations between these components of the oral ecosystem and the development of oral complications

Toelichting onderzoek

Achtergrond van het onderzoek

The oral cavity is a common site of acute and long term complications related to hematopoietic stem cell transplantation (HSCT). These complications cause significant morbidity and are associated with decreased quality of life. To date, management strategies for oral complications are mainly palliative and there is a great need for expanding the arsenal of preventative approaches.

Disturbed homeostasis of the oral cavity has been implicated as an important component of the pathogenesis of oral complications. Studies suggest that a less diverse microbiome, salivary output and proteins, and dental health influence the incidence and severity of oral mucositis and graft versus host disease. In addition, oral environment changes associated with graft versus host disease may increase caries risk. The H-OME study will expand the understanding of the role of the oral ecosystem in the onset, progression, and resolvement of these complications related to HSCT. This is attractive since many oral environment factors are modifiable and we anticipate that this knowledge will enable future development of improved and individualized preventative strategies.

Doel van het onderzoek

The oral environment (e.g., the oral microbiome and salivary proteome) contributes to the risk and severity of developing oral and dental complications (e.g., oral mucositis and oral graft versus host disease and dental diseases)

Onderzoeksopzet

Before, during and up to 18 months following hematopoietic stem cell transplantation

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Academic Medical Center Amsterdam

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult hematopoietic stem cell recipients

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients unable to give their informed consent

Patients younger than 18 years

Mismatched allogeneic transplantations

Caries study: edentulous patients

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-11-2015
Aantal proefpersonen:	102
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	16-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41813
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5645
NTR-old	NTR5760
CCMO	NL52117.018.15
OMON	NL-OMON41813

Resultaten

Samenvatting resultaten
A number of publications in peer reviewed scientific journals is planned to report the findings of this study