Oral complications of hematopoietic stem cell transplantation

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23941

Source
Nationaal Trial Register

Brief title
ORA-STEM/H-OME study

Health condition

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

stamceltransplantatie, mucositis, graft versus host ziekte, mondgezondheid

Sponsors and support

Primary 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

Source(s) of monetary or material Support: Dutch H-OME study: Koninklijk Wilhemina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Identification of other factors than the conditioning regimen to predict oral complications

Genetic polymorphisms involved in mucositis

Impact of oral complications on clinical and economic outcomes

Impact of oral complications on quality of life

Composition of the microbiome and any associations with incidence, severity and duration of oral mucositis and graft versus host disease

The composition of the salivary proteome and incidence and severity of oral mucositis and graft versus host disease
pre-existent periodontal disease and incidence, severity and duration of oral mucositis and graft versus host disease

Study description

Background summary

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.

Study objective

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)

Study design

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

Intervention

Not applicable

Contacts

Public
Academic Medical Center Amsterdam

JE Raber-Durlacher
Amsterdam
The Netherlands
Scientific
Academic Medical Center Amsterdam

JE Raber-Durlacher
Amsterdam
The Netherlands

Eligibility criteria

Inclusion criteria

Adult hematopoietic stem cell recipients

Exclusion criteria

Patients unable to give their informed consent

Patients younger than 18 years

Mismatched allogeneic transplantations

Caries study: edentulous patients

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-11-2015
Enrollment:	102
Type:	Unknown

Ethics review

Positive opinion

Date:	16-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41813
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

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