Oral complications in patients treated with hematopoietic stem cell transplantation

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Main study objectives:* To Identify the incidence, severity and temporal relationships of subjective and objective oral complications related to type of conditioning regimen in HSCT recipients* To determine which oral complications can predict...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON41813

Source
ToetsingOnline

Brief title
ORA-STEM

Condition

- Haematological disorders NEC

Synonym
oral complaints, oral side effect

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Hematopoietic stem cell transplantation, oral side effects

Outcome measures

Primary outcome

Main study parameters/endpoints:

* Conditioning regimen (full intensity versus reduced intensity regimens with or without total body irradiation) and characteristics of subjective oral complications (e.g., pain, xerostomia, dysgeusia, dysphagia measured by patient reported outcomes) and objective oral complications (e.g., mucositis, infections, hemorrhage, gingivitis, periodontitis, dental caries, osteonecrosis and GVHD measured by validated scales)
* Oral complications predictive for decreased QoL and negative clinical and economic outcomes (e.g., infections, use of antibiotics and opioid analgesics, parenteral nutrition, additional hospital visits, prolonged hospital stay, death)
* Genetic polymorphisms in candidate genes (microarray analysis of salivary DNA samples) predictive for severe OM and GVHD

Secondary outcome

Additional study parameters/endpoints of the Dutch side study:

* Alterations of the oral microbial community (identified by open-end next generation sequencing) and in the salivary flow and proteome (MALDI-TOF, 2D-SDS PAGE and Mass Spectometry) in HSCT recipients developing severe OM and oral GVHD compared with those who do not.
* Periodontal disease (measured by Plaque Index, Gingival Index, and

Periodontal Pocket depth) predictive for developing severe OM and GVHD

* Chronic oral GVHD and incidence and activity of dental caries (DMF-T and

ICDAS-II score)

* Alterations of the GI microbial community in HSCT recipients developing

severe GI mucositis (diarrhea and citrulline levels) compared with those who do

not

Study description

Background summary

The oral cavity is a common site of complications related to hematopoietic stem cell transplantation (HSCT). Oral complications have a negative impact on quality of life (QoL) and treatment outcomes. The knowledge on the incidence, severity, burden of illness and consequences of oral complications in HSCT is inadequate. This lack of clarity is reflected in a lack of effective oral management regimens. The present observational international multicenter study with the acronym *ORA-STEM* will be performed to attenuate the gap of knowledge on the clinical characteristics, consequences and risk factors of oral complications.
In addition, there is an urgent need to obtain a better insight in the role of the oral environment (e.g., pre-transplant dental pathologies, oral microbiome, salivary output and proteome) in the pathogenesis of oral complications. Moreover, there is a paucity of studies directed to potential associations between the oral and gastrointestinal (GI) microbiome, and their relative contribution to oral and GI mucositis. Therefore, the participating Dutch centers (AMC and RUMC) will perform a side study involving Dutch subjects only aimed at further unravelling the impact of the local ecosystem on complications in HSCT recipients.

We anticipate that the results will provide a scientific base for the development of individualized preventive strategies.

Study objective

Main study objectives:
* To Identify the incidence, severity and temporal relationships of subjective and objective oral complications related to type of conditioning regimen in HSCT recipients

* To determine which oral complications can predict negative clinical and economical outcomes and reduced QoL
* To explore whether genetic polymorphisms in candidate genes demonstrate an increased risk for the development of severe oral mucositis (OM) and graft versus host disease (GVHD)

Additional study objectives of the Dutch side study:
* To determine whether a less diverse oral microbiome is associated with increased incidence, severity, and duration of OM, and increased incidence and severity of acute and chronic oral GVHD
* To assess whether decreased salivary output and an aberrant salivary proteome are associated with increased incidence, severity, and duration of OM and increased incidence and severity of acute and chronic GVHD
* To determine whether pre-existent periodontal disease increases the incidence, severity and duration of OM and incidence and severity of acute and chronic oral GVHD
* To assess whether chronic oral GVHD is associated with increased incidence and activity of dental caries
* To explore potential associations between the oral and GI microbiome, and whether having a less diverse GI microbiome is associated with the incidence, severity, and duration of GI mucositis

Study design

Prospective observational multicenter study

Study burden and risks

The burden for patients is mild, as the study is observational, non-invasive and involves questionnaires and oral examination with collecting of oral rinsing and salivary samples before, during and after HSCT. Peripheral blood samples and rectal swabs will be collected together with those obtained for routine patient care as much as possible. There are no direct risks for participating subjects in this study. Patients may benefit from frequent structured oral assessments allowing early diagnosis of oral complications.

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

* Patients diagnosed with a hematological malignancy, who will receive FIC or RIC, followed by autologous or allogeneic HSCT
* Patients older than 18 years.
* Able and willing to provide written informed consent

Exclusion criteria

* Patients unable to give written informed consent.
* Patients younger than 18 years.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2015
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

ID: 23941
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52117.018.15
OMON	NL-OMON23941

Study results

Results posted: 20-05-2020

First publication
15-11-2019