THE ORAL CAVITY AS A SOURCE OF FEBRILE NEUTROPENIA

No registrations found.

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

Summary

ID

NL-OMON28600

Source
Nationaal Trial Register

Brief title
ORA-FEBRIS study

Health condition

Febrile neutropenia
Dental focus/foci

Febriele neutropenie
Dentogeen focus/foci

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Sponsor: Academic Medical Center

Intervention

Outcome measures

Primary outcome

To identify oral/dental foci prior to the start of chemotherapy and to determine whether these

are associated with the development of FN, bacteremia and/or SIRS/sepsis

Secondary outcome

To assess whether oral/dental foci are associated with the incidence and severity of OM

To assess whether OM is associated with FN, bacteremia and SIRS/sepsis

To document microbiological shifts (bacteria/fungi) in oral rinsing samples taken prior to chemotherapy and during standard care visits thereafter using an innovative open-end technique and to investigate any associations with the development of OM

To assess retrospectively whether any microorganisms found in blood samples from patients with FN are (likely) derived from the oral cavity using DNA finger printing techniques and Q-PCR.

To explore whether genetic polymorphisms in candidate genes demonstrate an increased risk for the development of severe OM, FN, and SIRS/sepsis

Differences in inflammation parameters in peripheral blood at baseline and when presenting with fever and/or mucositis.

Study description

Background summary

ebrile neutropenia (FN) is a clinically important adverse effect of myelosuppressive chemotherapy. If patients present with FN, attention is focussed on well-recognized sites of origin of infection: the airways, urinary tracts, and skin. However, infections can be only documented clinically in about two-third of febrile episodes, whereas a causative microbial pathogen cannot be identified in the majority (>70%) of cases.
Pre-treatment oral evaluation aimed to identify and eliminate oral/dental foci is only routinely used in patients at high risk for oral complications (i.e. head and neck cancer patients and stem cell transplantation recipients). However, any patient treated with myelosuppressive chemotherapy, be it for cure or palliation, is at risk of developing infection in and/or originating from the oral cavity. Nevertheless, in these patients dental screening is somewhat randomly employed at the oncologist’s discretion.

More insight into the pre-treatment oral condition and its potential role in FN is mandatory, particularly considering the growing numbers of older patients retaining their natural dentition and the increase of dental diseases and cancer incidence with age.

In addition, oral diseases may aggravate chemotherapy-induced oral mucositis (OM). OM is associated with an inflammatory response, which together with ulcerations providing a portal

of entry for bacteria, can result in FN and systemic inflammatory syndrome (SIRS) and/or sepsis. Evidence suggests that microorganisms are involved in the pathobiology of OM, but no longitudinal studies using open-end sequencing are available.

Furthermore, comparing bacteria identified in blood cultures in febrile patients with those of the oral cavity will expand our knowledge on the role of the oral cavity as a potential source of bacteremia.

We expect that our results will provide a scientific base for subsequent intervention studies on the efficacy of dental screening and elimination of foci, and other interventions aimed at modifying the oral environment before and during chemotherapy.

Study objective

The oral cavity plays a role in the development of febrile neutropenia in patients treated with myelosuppressive chemotherapy

Study design

Dental examination prior to first cycle of chemotherapy

During and after chemotherapy clinical examination of the oral mucosa and oral rinsing sample (until 100 days after first chemotherapy)

Intervention

none

Contacts

Public
Academisch Medisch Centrum - Kamer A1-130

J.A.E.M. Zecha
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5661835
Scientific
Academisch Medisch Centrum - Kamer A1-130

J.A.E.M. Zecha
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5661835

Eligibility criteria

Inclusion criteria

- Diagnosed with a solid cancer, lymphoma or multiple myeloma

- Planned treatment with myelosuppressive chemotherapy with FN risk of 10%-20% (with or without targeted therapies or hormonal therapy)

- Willing and able to give written Informed consent

- Age 18 or older

- Presence of (partial) natural dentition and/or dental implants

Exclusion criteria

- Patients unable to give written informed consent

- Patients <18 years

- Prior irradiation to the head and neck - Edentulous patients

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

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

Study registrations

Followed up by the following (possibly more current) registration

ID: 50743
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5646
NTR-old	NTR5761
CCMO	NL53440.018.15
OMON	NL-OMON50743

Study results