THE ORAL CAVITY AS A SOURCE OF FEBRILE NEUTROPENIA

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

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

Samenvatting

ID

NL-OMON28600

Bron
Nationaal Trial Register

Verkorte titel
ORA-FEBRIS study

Aandoening

Febrile neutropenia
Dental focus/foci

Febriele neutropenie
Dentogeen focus/foci

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Sponsor: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients unable to give written informed consent

- Patients <18 years

- Prior irradiation to the head and neck - Edentulous patients

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50743
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten