Smell and Taste Dysfunction in Children with Cancer

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Smell function, taste function, and papillae density will decrease in childhood cancer patients during chemotherapy compared to: 1) The period before chemotherapy, 2) Controls (siblings).

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

Samenvatting

ID

NL-OMON25750

Bron
Nationaal Trial Register

Verkorte titel
SENSORY

Aandoening

Childhood cancer patients

Ondersteuning

Primaire sponsor: Princess Máxima Center
Overige ondersteuning: Princess Máxima Center, Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is feasibility of the study. Therefore we will test whether the lower age range is suitable to be tested. If not, for our next studies we will increase the lower age

limit. The number of patients fully completing the study is the main endpoint.

Toelichting onderzoek

Achtergrond van het onderzoek

Children with cancer experience chemosensory changes (i.e., changes in their sense of taste and smell) during the course of treatment. Irradiation of head and neck, and administration of chemotherapeutic agents induce these changes. This is an often overlooked but still important treatment symptom as it contributes to poor food intake which in turn may cause malnutrition and affect prognosis. The central aim of this project is to elucidate causes and consequences of chemosensory changes in childhood cancer patients. The reasons for examining children with cancer (as opposed to adults) are that (1) there is very little known of the impact cancer treatment has on children’s sense of taste and smell and how this affects food intake and food preferences directly and on the longer term; (2) dietary habits and flavour preferences are still developing in children and thus the impact of therapy induced dysfunctional taste and smell is, presumably, much larger in childhood cancer patients.

Doel van het onderzoek

Smell function, taste function, and papillae density will decrease in childhood cancer patients during chemotherapy compared to: 1) The period before chemotherapy, 2) Controls (siblings).

Onderzoeksopzet

Patients: measurements (smell, taste, papillae density) will take place during clinical admission to the hospital, at least once in every patient.
- Measurement 1: before a cycle of chemotherapy (day 1), in order to explore whether measurements are feasible.
- Measurement 2: at the end of the cycle of chemotherapy, only if the first measurement can be considered as feasible.

Controls: one measurement.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria patients:
- Children, 6-17 years old
- Currently undergoing chemotherapy

Inclusion criteria controls (siblings):
- Children, 6-17 years old

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria patients:
- Children with isolated congenital anosmia (ICA; a complete loss of smell)
- Children ≤ 5 years
- Children and parents that do not understand the Dutch language
- Children with a self-reported allergy to quinine
- Children with severe oral mucositis (treatment-induced ulceration of the mucosa, blis-tered tongue, and absence of saliva)

Exclusion criteria controls:
- Children with isolated congenital anosmia (ICA; a complete loss of smell)
- Children ≤ 5 years
- Children and parents that do not understand the Dutch language
- Children with a self-reported allergy to quinine

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7533
Ander register	METC UMCG : METC2018/621

Resultaten