Smell and Taste Dysfunction in Children with Cancer

No registrations found.

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

Summary

ID

NL-OMON25750

Source
Nationaal Trial Register

Brief title
SENSORY

Health condition

Childhood cancer patients

Sponsors and support

Primary sponsor: Princess Máxima Center
Source(s) of monetary or material Support: Princess Máxima Center, Maastricht University

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Smell function
- Taste function
- Subjective smell and taste function (questionnaire)
- Papillae density
- Eating behaviour

Study description

Background summary

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.

Study objective

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).

Study design

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results