A prospective Study on prevalence and determinants of Ototoxicity dUring treatmeNt of childhooD cancer

No registrations found.

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

Summary

ID

NL-OMON23866

Source
NTR

Brief title
SOUND

Health condition

Central nervous system tumor or solid tumor

Sponsors and support

Primary sponsor: Trial Data Center Princes Màxima Center for pediatric oncology
Source(s) of monetary or material Support: PMC / Crowd-funding

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to determine the prevalence of children with hearing loss at time of discontinuation of cancer therapy in a prospective full cohort of 600 children

with solid and CNS tumors

Secondary outcome

The secondary objectives of this study are:
- To study the feasibility of standard of care audiological (hearing loss, tinnitus and vertigo) testing of all patients with solid and CNS tumors treated with platinum, CNS-/ENT irradiation, CNS-/ENT surgery, before and after childhood cancer therapy by using standardized diagnostic tests, timing and frequency of audiological evaluations in this population (stratum 1).
- To gain insight into the relative contribution of cancer treatment components, clinical characteristics and supportive care co-treatment (aminoglycosides, loop diuretics, and vancomycin) on hearing loss in children with solid and CNS tumors that doreceive platinum derivates and/or CNS-/ENT irradiation, and/or CNS/ENT surgery, by performing standard audiological testing at the end of treatment (stratum 1).
- To gain insight into the relative contribution of supportive care medication (aminoglycosides, loop diuretics, and vancomycin) on hearing loss in children with solid and CNS tumors that do not receive platinum derivates and/or CNS-/ENTirradiation and/or CNS/ENT surgery, by performing audiological testing at the end of treatment (stratum 2).
- To determine the effect of platinum dose and levels, irradiation dose, co-medication dose and levels on ototoxicity at the end of treatment (stratum 1).
- To gain insight in the frequency and characteristics of patients with abnormalities in audiological testing (hearing loss, tinnitus and vertigo) occurring during childhood solid tumor and CNS cancer treatment (stratum 1 and 2).
- To create a registry with outcomes of audiological evaluations and potential determinants for ototoxicity during childhood cancer therapy (stratum 1 and 2), which can be used for further research on innovation and enhancing of audiological testing and genetic susceptibility studies.

Study description

Background summary

In The Netherlands, approximately 600 children are diagnosed with childhood cancer annually. Childhood cancer survival rates reach up to about 75-80% because of beter stratification and treatment. Ototoxicity, which includes hearing loss, tinnitus and vertigo, is one of the direct and late sides effects of cancer treatment. Over the past few years, it has become apparent that platinum agents, CNS (Central Nervous System)-/ENT (Ear-Nose-Throat) surgery and CNS-/ENT irradiation are important risk factors for ototoxicity. Irreversibel hearing loss occurs in up to 80% of childhood cancer survivors that had received platinum agents. Tinnitus has been reported in up to 17% of childhood cancer patients and survivors. At this moment large national prospective cohorts of childhood cancer patients that were systematically screened for ototoxicity have not been reported, this hampers estimation of true frequencies and determinants like comedication such as antibiotics and

diurects which are often prescribed in oncology treatment protocols. Determining prevalence and risk factors for ototoxicity will give insight in which children will qualify for audiological screening in the future, and what kind of interventions can be used to prevent ototoxicity.

In the SOUND study 600 solid tumor/ CNS tumor patients will be identified in two years. Patients will be devided into 2 strata, stratum 1 contains of patients treated with CNS-/ENT surgery, CNS-/ ENT irradiation and/or treatment with platinum agents. Stratum 2 consists of the remaining group of patients who do not receive platinum treatment and/or CNS-/ENT irradiation and/or CNS-/ENT surgery, but will receive supportive care medication often applied for fluid overload or serious infections. All included patients will be audiological evaluated at baseline (before start of cancer treatment) and within 3 months after end of cancer treatment. For both strata data of potential ototoxic determinants will be collected during treatment.

Study objective

We will identify clinical and cancer treatment related risk factors associated with hearing loss, tinnitus and vertigo.
We will determine the prevalence of hearing loss, tinnitus and vertigo in a prospective cohort of CNS/ solid tumor patients.

Study design

Before start of cancer treatment and within 3 months after cancer treatment

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in stratum 1, a subject must meet all of the following criteria:
1. Diagnosed with a CNS tumor or solid tumor in the Princess Máxima Center and
2. Planned to receive treatment with cisplatin and/or carboplatin and/ or oxaliplatin and/or CNS-/ENT irradiation
and/or CNS-/ENT surgery and
3. Children aged 0 until 19 years at time of diagnosis.
4. Biobank/ "over de drempel PIF", Informed Consent Form (ICF) signed for collection of standard of care data.

In order to be eligible to participate in stratum 2, a subject must meet all of the following criteria:
1. Diagnosed with a CNS tumor or solid tumor in the Princess Máxima Center and
2. Not planned to receive treatment with cisplatin and/or carboplatin and/or oxaliplatin and/or CNS-/ENT
irradiation and/or CNS-/ENT surgery and
3. Children aged 0 until 19 at time of diagnosis and
4. Study specific informed consent form (ICF) signed prior to participation in the study.

Exclusion criteria

Critically ill, Intensive Care unit admission because of which audiological evaluation is not possible before
start chemotherapy and/or CNS-/ENTradiotherapy and/or CNS-/ENT surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2020
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	07-09-2020
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	NL8881
Other	METC-Utrecht : METC 20-417/M

Study results