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

Gepubliceerd: 07-09-2020 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON23866

Bron
NTR

Verkorte titel
SOUND

Aandoening

Central nervous system tumor or solid tumor

Ondersteuning

Primaire sponsor: Trial Data Center Princes Màxima Center for pediatric oncology
Overige ondersteuning: PMC / Crowd-funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

Princess Máxima Center
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	07-09-2020
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	NL8881
Ander register	METC-Utrecht : METC 20-417/M

Resultaten