Monitor Immune Microenvironment and systemic immune effects in pediatric Brain tumors

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

Samenvatting

ID

NL-OMON24486

Bron
NTR

Verkorte titel
MIMIC Brain

Aandoening

Pediatric brain tumors

Ondersteuning

Primaire sponsor: Princess Máxima Center for Pediatric Oncology
Overige ondersteuning: Stichting Team Westland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Descriptive characterisation of lymphoid and myeloid subsets and activation status in different compartment, e.g. tumor microenvironment, blood, bone marrow, and CSF at different timepoints

Toelichting onderzoek

Achtergrond van het onderzoek

Cellular therapy and immune modifying interventions, e.g. checkpoint inhibition and antibody or CAR T-cell therapy show promising results in adult and pediatric tumors with a previously dismal prognosis. Whereas cellular therapy has been demonstrated to be effective in pediatric acute lymphoblastic leukemia, the efficacy of immunotherapy in neuro oncology needs to be further exploited. A thorough understanding of the tumor microenvironment and its influence on the immune system is the first step in the translation of preclinical immuno-oncology research into clinical trials.

Doel van het onderzoek

The aim is to characterize the immune infiltrate in the tumor microenvironment and to study the influence of the tumor on immune parameters in different compartments e.g. blood, bone marrow, CSF and faeces. In addition, a broad spectrum of immune parameters will be followed during treatment in different body compartments to describe the influence of therapy (surgery, radiotherapy and chemotherapy). At last, target finding will be incorporated in this project as an exploratory endpoint.

Onderzoeksopzet

- Screening baseline
- Resection or biopsy = day 0
- Day 14 +/-7 days
- 3 months +/- 4 weeks
- 6 months +/- 6 weeks
- 12 months +/- 8 weeks = end of monitoring
- Relapse

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 0 – 18 years at inclusion
- Newly diagnosed brain tumor or relapse of a brain tumor
- MRI representing an image of a high grade brain tumor (high grade glioma, ependymoma, ATRT, medulloblastoma, or otherwise high grade) OR CNS tumor where based on MRI images the judgement of high grade versus low grade can’t be made. NB in case MRI imaging prior to biopsy and/or resection is not feasible, the patient can be included based on CT imaging and clinical assessment
- Clinical indication for tumor biopsy/resection
- Written (parental) informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Suspected germ cell tumor on radiology or based on tumor markers (αFP, βHCG)
- Suspected craniopharyngioma on radiology
- Clear characteristics of low grade tumor

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	14-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52105
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8967
CCMO	NL75515.041.21
OMON	NL-OMON52105

Resultaten