Immunomonitoring in neuroblastoma patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24604

Source
NTR

Brief title
immunoNB

Health condition

Neuroblastoom, immuuntherapie, farmacokinetiek van dinutuximab
Neuroblastoma, immunotherapy, pharmacokinetics of dinutuximab

Sponsors and support

Primary sponsor: Prinses Máxima Centrum
Source(s) of monetary or material Support: Kika

Intervention

Outcome measures

Primary outcome

The primary objective is to gain data on the different responses of the immune system between patients during (immune)therapy by exploring the presence, phenotype and function of multiple immune cell subsets in peripheral blood:

1. Regulatory T-cells

2. Natural Killer cells

3. Effector/memory T-cells

4. Thelper-cells

5. B-cells

6. Dendritic cells

7. Myeloid derived suppressor cells

Secondary outcome

The secondary objectives are the following:

1. If possible, we will compare immune status of patients with progressive or relapsed disease, with patients that remained disease-free throughout and following the completing of therapy.

2. Explore the variation in CH14.18 levels between patients and between treatment cycles and validate the current detection method (via liquid chromatography tandem-mass spectrometry).

3. We will study the PK and pharmacodynamics properties of CH14.18 (and GM-CSF and IL-2) in NBL patients and if applicable relate exposure parameters to efficacy and toxicity.

Study description

Study design

Not applicable

Intervention

In this study there are no interventions. We will collect extra blood (5 ml) one time (for low risk and medium risk neuroblastoma patients) or 18 times (for high risk neuroblastoma patients) during the treatment (spread over 1.5 years)

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

* Signed informed consent

* Newly diagnosed NBL, histologically proven diagnosis

* Initial staging of the tumor

* Between 1-18 years old at diagnosis

Exclusion criteria

* Incomplete informed consent

* Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52494
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7362
NTR-old	NTR7571
CCMO	NL66764.078.18
OMON	NL-OMON52494

Study results

Summary results
El Amrani M, Szanto CL, Hack CE, Huitema ADR, Nierkens S, van Maarseveen EM.Quantification of total dinutuximab concentrations in neuroblastoma patients with liquid chromatography tandem mass spectrometry. Anal Bioanal Chem. 2018;1–10