Minimal residual disease monitoring in PTLD

Gepubliceerd: 23-07-2018 Laatst bijgewerkt: 18-08-2022

MRD detection using next generation sequencing (NGS) on circulating tumor DNA (ctDNA) from PTLD patients using a gene panel previously used in diffuse large B-cell lymphoma (DLBCL) may be feasable

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

Samenvatting

ID

NL-OMON22796

Bron
Nationaal Trial Register

Aandoening

Circulating tumor DNA
Post-transplant lymphoproliferative disorder
18F-flurodeoxyglucose positron emission tomography/computed tomography
Minimal residual disease

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: UMCG Kanker Researchfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Detection of ctDNA at diagnosis and response evaluation

Toelichting onderzoek

Achtergrond van het onderzoek

Post-transplant lymphoproliferative disorder (PTLD) is a serious complication after solid organ (SOT) and hematopoietic stem cell transplantation (HSCT), associated with significant morbidity and mortality. Initial treatment consists of tapering immune suppression and rituximab monotherapy. 18F-flurodeoxyglucose positron emission tomography/computed tomography (18F-FDG-PET/CT) has become the main tool to assess remission status, drive decisions on treatment alteration and identify relapse in patients with PTLD. In case of positive 18F-FDG-PET/CT following rituximab, treatment is escalated with R-CHOP. However 18F-FDG-PET/CT false positives results are commonly reported and it has limited prognostic value (positive predictive value of 38% negative predictive value of 92%). Minimal residual disease (MRD) from circulating tumor DNA (ctDNA) fragments occurs under the detection threshold of 18F-FDG-PET/CT. With a blood sample one may be able to monitor MRD, thought to be responsible for disease progression and relapse. MRD may become an early response indicator used to guide treatment. We will investigate the feasibility of MRD monitoring in PTLD patients and perform an exploratory study to evaluate if MRD monitoring may be used to trace disease status during treatment and identify early responders from (non-) responders.

Doel van het onderzoek

MRD detection using next generation sequencing (NGS) on circulating tumor DNA (ctDNA) from PTLD patients using a gene panel previously used in diffuse large B-cell lymphoma (DLBCL) may be feasable

Onderzoeksopzet

Diagnosis Interim, After 2x R-CHOP, End-of treatment

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients having undergone a SOT or HSCT

- Histologically proven CD20+ monomorphic PTLD (with or without EBV association),

- Age > 18 years

- Intent to treat patient according to standard protocol (rituximab / R-CHOP). Clinicians are allowed to adapt protocol in the best interest of the patient

- Measurable disease on 18F-FDG-PET/CT at diagnosis according to the Lugano classification 2014

- Patient’s written informed consent and written consent for data collection.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- A complete surgical resection of tumor.

- Upfront treatment with external beam radiation therapy.

- Involvement of the central nervous system by the disease.

- Known to be HIV positive.

- Iatrogenic immunodeficiency lymphomas other than PTLD.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-07-2018
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	NL7203
NTR-old	NTR7402
Ander register	UMCG register : 201800427

Resultaten