Minimal residual disease monitoring in PTLD

No registrations found.

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

Summary

ID

NL-OMON22796

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: UMCG Kanker Researchfonds

Intervention

Outcome measures

Primary outcome

Detection of ctDNA at diagnosis and response evaluation

Secondary outcome

- Sensitivity and specificity of plasma ctDNA genotyping in comparison with tumor sample

DNA (gDNA) as gold standard

- Changes in ctDNA abundance throughout therapy

- Clinical end-points: progression free survival (PFS), overall survival (OS), event free survival (EFS), disease specific survival (DSS)

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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.

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):	01-10-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-07-2018
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	NL7203
NTR-old	NTR7402
Other	UMCG register : 201800427

Study results