Immune monitoring after anti-CD19 CAR T-cel therapy with patients with B-cell NHL

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To determine the factors that contribute to response to CAR T-cell therapy, both at the tumour-end, as well as on the T-cell side to understand mechanisms of efficacy and immune escape in order to optimize this treatment and to reduce toxicity

Ethical review	Approved WMO
Status	Pending
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56841

Source
ToetsingOnline

Brief title
Anti-CD19 CAR T-cell therapy monitoring study

Condition

- Haematological disorders NEC

Synonym
B-cell NHL, B-cell non-Hodgkin lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anti-CD19 CAR T-cel therapy, B-cell NHL, Hematology, Immune monitoring

Outcome measures

Primary outcome

Overall objective response rate

Correlation of cell free tumor DNA with ORR

T-cell persistence combined with immunological and metabolic phenotype

Observation of T-cell immune evasion mechanisms in tumor area

Secondary outcome

No secondary parameters

Study description

Background summary

Anti-CD19 CAR T-cell therapy has revolutionized the treatment of B-cell lymphoma, B-ALL and B-CLL and two product are currently registered by EMA and the FDA. Although results are impressive, not all patients benefit and toxicity can be severe. Although several mechanisms of failure to respond to CAR T-cell therapy and/or relapse following initial response are known, such as loss of antigen, lack of persistence or T-cell exhaustion, we have limited understanding of how we can predict failure or success. In order to get better understanding of the mechanisms of CAR T-cell resistance we need to archive and store blood and tissue, combined with clinical data, of all patients that are undergoing this treatment.

Study objective

To determine the factors that contribute to response to CAR T-cell therapy, both at the tumour-end, as well as on the T-cell side to understand mechanisms of efficacy and immune escape in order to optimize this treatment and to reduce toxicity

Study design

Prospective interventional study of patients that are treated with standard of care CAR T-cell therapy for B-cell NHL

Study burden and risks

Peripheral blood will be collected at routine visits and toxicity visits. Extra material will be collected but no additional vena puncture will have to be done
Tumor tissue will be collected necessary for diagnosis or confirmation of relapse. If archival material is available and new biopsy is not feasible, this material will be used.
At day 15 post infusion of CAR T-cells a biopsy will be attempted if risks for patient are minimal.

If a patient developes 'immune effector cell (IEC) associated neurotoxicity syndrome', a lumbar puncture will have to be performed as part of standard care to exclude other causes of neurological complaints such as infection. as part of this routine puncture an additional liquor tube will be collected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

treatment of B-cell NHL with anti-CD19 CAR T-cel therapy

Exclusion criteria

no informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	525
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-04-2021
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL74209.078.20