Clinical and biological follow-up of children and young adutls prior to, during, and after CAR T-cell therapy, prospective single-centre study (CABRIO)

Published: 09-01-2025
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To determine the real world response to standard of care CAR T-cell therapy, in order to better understand the intrinsic and extrinsic factors related to treatment success or failure.

Ethical review	Approved WMO
Status	Pending
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON57230

Source
ToetsingOnline

Brief title
CABRIO: learning from CAR T-cell therapy to make better use of it

Condition

- Leukaemias

Synonym
CAR T-cell therapy, Cellular therapy, Immune therapy

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: KIKA

Intervention

Keyword: CAR T-cells, Cellular therapy, Immune monitoring, Pediatric oncology

Outcome measures

Primary outcome

The primary endpoint of the study is to characterize and quantify changes in

the immune response during CAR T-cell treatment.

Secondary outcome

Secondary endpoints will include the impact of fludarabine levels on the immune

profile, CAR T-cell expansion, CAR T-cell persistence and quality of life.

Study description

Background summary

The treatment of relapse and refractory B-cell precursor- acute lymphoblastic leukaemia (BCP-ALL) in children is changing since the introduction of immunotherapy. Chimeric antigen receptor T (CAR T) cell therapy was rapidly introduced after EMA approval based on the positive results of CTL019 in refractory or relapsed after stem cell transplantation BCP-ALL.(Maude NEJM 2018) The recent introduction of this viral transduced, ex vivo expanded product, warrants an extensive long-term follow-up of patients of real-world data. This includes efficacy data, and scientific research - specifically immune monitoring, to improve the efficacy, quality of life aspects and the documentation of side effects of this novel treatment. The aim is to register these data in a prospective CAR T cell registry.

Study objective

To determine the real world response to standard of care CAR T-cell therapy, in order to better understand the intrinsic and extrinsic factors related to treatment success or failure.

Study design

Prospective longitudinal observational study of patients treated with CAR T cell therapy in the Princess Máxima Center for pediatric oncology. Stratum A includes children treated with tisagenlecleucel in standard of care setting for BCP-ALL. Additional strata will be amended in case other CAR T cell products receive market approval.

Study burden and risks

This study aims to collect clinical data in combination with biological samples prior to and after CAR-T cell infusion. After consent a bone biopsy will be performed during the standard bone marrow aspiration and therefore patients will not be exposed to additional procedures. The volume of blood that is withdrawn for the study does not exceed the recommended maximum.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Age 0-26 years
2. Intention to start CAR T-cell treatment in Princess Máxima Center
3. Signed written informed consent
4. Stratum specific inclusion criteria
• Stratum A: tisagenlecleucel in standard of care treatment for BCP-ALL
• Other strata will be amended after market approval
• Strata for patients in clinical studies will be amended

Exclusion criteria

No informed consent obtained

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-01-2025
Application type:	First submission
Review commission:	METC NedMec

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
Other	ISRTCN wordt definitief na goedkeuring
CCMO	NL87682.041.24