Long-term follow-up of patients previously treated with autologous T cells genetically modified with retroviral vectors.

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Primary Objective:- Long-term safetySecondary Objective:- Survival- Clinical efficacy of AUTO CAR T cell therapy in patients enrolled prior to disease progression- Chimeric antigen receptor (CAR) transgene persistence- Replication competent...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46028

Source
ToetsingOnline

Brief title
Long-term follow up of patients treated with a CAR T-cell

Condition

- Other condition
- Leukaemias

Synonym
Cancer

Health condition

Plasma Cell Neoplasm, Lymphomas non-Hodgkin's B-cell, Lymphomas non-Hodgkin's T-cell and Leukaemias

Research involving
Human

Sponsors and support

Primary sponsor: Autolus Limited
Source(s) of monetary or material Support: Autolus Limited

Intervention

Keyword: Cancer, Chimeric Antigen Receptor (CAR)-T cell, Delayed adverse events, Long-term Safety

Outcome measures

Primary outcome

- Incidence of serious adverse events related to AUTO CAR T cell therapy.

- New malignancies.

- Other designated adverse events of special interest to AUTO CAR T cell

therapy

Secondary outcome

- Overall survival for up to 15 years after the first AUTO CAR T cell therapy

infusion.

- Duration of response, progression free survival.

- Proportion of patients with detectable vector copy number in peripheral

blood, up to 15 years after the first AUTO CAR T cell therapy infusion.

- Confirm / monitor for absence of detectable RCR, up to 15 years after the

first AUTO CAR T cell therapy infusion.

- In case of new malignancy: Insertion site analysis to determine insertional

mutagenesis as potential cause/contributor in case of new malignancy.

Study description

Background summary

Patients exposed to an investigational gene therapy product (e.g. AUTO CAR T cell therapy) on a treatment study, may be subject to long-term risks and therefore these patients must be followed up long-term for any delayed Serious Adverse Events (SAEs) related to treatment with gene therapy products.
The purpose of this study is to monitor all patients exposed to an existing and authorised AUTO CAR T cell therapy, as well as the Sponsor*s future autologous T cell products using the same Moloney Murine Leukaemia based retroviral vector, for up to 15 years following their first AUTO CAR T cell therapy infusion to assess the risk of delayed SAEs, adverse events of special interest (AESIs), monitor for emergence of replication competent retrovirus (RCR), and assess long-term efficacy, including CAR transgene persistence.
Monitoring of such long-term effects of AUTO CAR T cell therapy will help to further define the risk-benefit profile of these new CAR T cell therapies.

Study objective

Primary Objective:
- Long-term safety

Secondary Objective:
- Survival
- Clinical efficacy of AUTO CAR T cell therapy in patients enrolled prior to disease progression
- Chimeric antigen receptor (CAR) transgene persistence
- Replication competent retrovirus (RCR) emergence
- Insertional mutagenesis

Study design

Patients will be enrolled following completion or early discontinuation from an AUTO CAR T cell therapy treatment study and will be followed for up to 15 years (or death, whichever happens first) after the first AUTO CAR T cell therapy infusion. Patients will be monitored for safety, as described in the primary outcome measures, every 3 months for the year following the first AUTO CAR T cell therapy infusion, then every 6 months for the next 4 years and then annually for the following 10 years.

Study burden and risks

Possible adverse effects/discomforts related to blood samples collection

throughout the study.

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

•Patients must have received an AUTO CAR T cell therapy on a clinical treatment study.
•Patients must have provided informed consent for long-term follow-up study prior to participation.
•Patients must be able to comply with the study requirements.

Exclusion criteria

- There are no specific exclusion criteria for this study.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	22-08-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-11-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	CANC 36926
EudraCT	EUCTR2016-004867-38-NL
CCMO	NL66404.000.18