Long-Term Follow-Up (LTFU) of Participants Treated with Adoptive Cell Therapies (study 208750)

Published: 27-08-2019
Last updated: 07-09-2024

This study has been transitioned to CTIS with ID 2024-513033-21-00 check the CTIS register for the current data. Primary:• To monitor participants for delayed AEs associated with administration of autologous cells that have been genetically modified...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON52738

Source
ToetsingOnline

Brief title
208750

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer; tumors

Research involving
Human

Sponsors and support

Primary sponsor: Adaptimmune LLC
Source(s) of monetary or material Support: Adaptimmune LLC

Intervention

Keyword: Adoptive Cell Therapies, Follow-up, lentiviral vector, Long term

Outcome measures

Primary outcome

Delayed adverse events.

Secondary outcome

RCL, modified cells or integrated vector sequences and integration patterns in

peripheral blood. Incidence of death and time of death.

Study description

Background summary

Adoptive T-cell therapy (ACT) is a therapeutic approach that uses a cancer patient*s own T lymphocytes obtained by leukapheresis, genetically engineered using a lentiviral vector to express a tumor specific T-cell receptor, expanded in vitro and re-infused into the participant, with the aim of generating an anti-tumor T-cell immune response. NY-ESO-1 and LAGE-1a antigens are tumor-associated proteins that have been found in several tumor types, including non-small cell lung cancer (NSCLC). Previous clinical trials using ACT with T-cells directed against NY-ESO-1/LAGE-1a have shown objective responses between 40-60% in participants with synovial sarcoma, metastatic melanoma, and multiple myeloma. Pembrolizumab is a monoclonal antibody that acts specifically on tumor targeting T-cells to block PD-1/PD-L1 interaction and increase T-cell anti-tumor function; pembrolizumab will be used in combination with NY-ESO-1/LAGE-1a TCR engineered patient T-cells (GSK3377794) to potentially further improve therapy for patients.
The ability of GSK3377794 to achieve objective responses in diverse tumor types supports a hypothesis that HLA and antigen expression are biomarkers that identify a population of participants that may benefit from GSK3377794.
Patients that have been exposed to genetically modified agents like GSK3377794, must be minitored for long term safety of the agent during 15 years after administration. The current study is this long term follow-up protocol for all parent studies with GSK3377794. For The Netherlands two parent studies are currently in preparation: protocol 208467 (NL70428.000.19, solid tumors) and protocol 208471 (NL69764.000.19, non-small cell lung cancer).

Protocol amendment 3, August 2021:
The primary reason for this amendment::
To allow for the inclusion of participants who have been treated with adoptive cell therapies across all GSK-sponsored or supported studies or as part of managed access to a GSK adoptive cell therapy agent, to include pediatric assessments into the protocol, clarify timings for the collection of PROs, clarify the definition and types of delayed AEs to report, harmonize the RCL, persistence of gene modified cells, and supportive care guidance sections with other GSK cell therapy protocols, and to make minor administrative updates.
For NL this means that trial subjects from the 2nd Dutch study (Gen-2, NL74331.000.20 with the treatments GSK3845097 and GSK3901961) are also eligible for this follow up study.

Protocol amendment 4 (September 2023) to:
Change of sponsorship from GlaxoSmithKline (GSK) to Adaptimmune.

Study objective

This study has been transitioned to CTIS with ID 2024-513033-21-00 check the CTIS register for the current data.

Primary:
• To monitor participants for delayed AEs associated with administration of autologous cells that have been genetically modified by lentiviral vectors
Secondary:
• To monitor Replication Competent Lentivirus (RCL).
• To measure persistence of genetically modified cells in the body.
• Assess the pattern of vector integration sites if at least 1% of cells in the surrogate sample are positive for vector sequences by polymerase chain reaction.
• To monitor survival status.

Study design

Non-therapeutic, multicenter, long-term follow-up study (LTFU).
Follow-up duration until 15 years after the administration of adoptive T-cell therapy. In participants undergoing a second treatment with adoptive T-cell therapy, the 15-year follow up will start after the second infusion.
Time spent in the parent study after the administration of adoptive T-cell therapy will be deducted from the 15 years follow-up period.
Visits every 6 months during the first 5 years and every 12 months thereafter.
LTFU protocol will remain open until all participants enrolled have been followed for 15 years following adoptive T-cell therapyor until death.
The number of participants enrolled in this study will depend on the number of participants receiving adoptive T-cell therapy in the parent protocol(s).

Study burden and risks

Risk: None.
Burden:
Visits every 6 months during the first 5 years (and after the first 3 months) and every 12 months thereafter.
• Physical examination: every visit.
• Blood tests (8-30 ml per occasion): every visit.
• Questionnaires: QLQ-C30, EQ-5D-3L: every visit.
Optional:
• Photographs of skin abnormalities in case of adverse events.

Contacts

Public
Adaptimmune LLC

Rouse Blvd 351
Philadelphia PA 19112
US
Scientific
Adaptimmune LLC

Rouse Blvd 351
Philadelphia PA 19112
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Had at least one dose of Adoptive Cell Therapies in the parent study.

• Have either completed the interventional study or have withdrawn from it.
• Contraception guidelines for males and females should be followed, see chapter 5.1 of the protocol for details.

Exclusion criteria

None

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-01-2026
Enrollment:	1
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	GSK3377794
Generic name:	Letetresgene autoleucel
Product type:	Medicine
Brand name:	GSK3845097
Generic name:	GSK3845097
Product type:	Medicine

Brand name:	GSK3901961
Generic name:	GSK3901961

Ethics review

Approved WMO Date:	27-08-2019
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-01-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-11-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-03-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-08-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-08-2021

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-12-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-11-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-12-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-02-2024
Application type:	Amendment
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
EU-CTR	CTIS2024-513033-21-00
EudraCT	EUCTR2018-004888-31-NL
ClinicalTrials.gov	NCT03391778
CCMO	NL70429.000.19