A phase 2 immunoPET imaging study with ZED88082A/CED88004S in patients with Large B-cell lymphoma before and after CD19-directed CAR T-cell therapy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21584

Source
Nationaal Trial Register

Brief title
CD8 Imaging CAR T

Health condition

Large B-cell Lymphoma

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: Genen Tech Inc

Intervention

Outcome measures

Primary outcome

- To determine the whole-body biodistribution of the ZED88082A tracer in normal tissues and

tumor lesions before and after CAR T-cell therapy.

Secondary outcome

- Assess safety and dosimetry ZED88082A/CED88004S uptake in the setting of CD19-directed CAR T-cell therapy
- Correlative expression analysis between ZED88082A tracer standard uptake volume (SUV) parameters in the tumor, CD8 expression in tumor biopsy, and response to CAR T-cell therapy.
- To perform correlative expression analysis between SUV parameters of ZED88082A tracer in the tumor, CD8 expression in tumor biopsy, and SUV parameters in the tumor and whole-body and CAR T-cell persistence, peak level and CAR T-cell phenotype as measured in the peripheral blood.
- Correlative expression analysis between ZED88082A tracer SUV parameters in the tumor, and grade 1-5 adverse events to CAR T-cell therapy, including cytokine release syndrome and neurotoxicity.
- Correlative expression analysis between ZED88082A tracer uptake in irradiated versus non-irradiated lymphoma lesions in patients who require radiotherapy as bridging strategy prior to CAR T-cell infusion.

Study description

Background summary

This is a single-center, single-arm trial designed to evaluate the distribution of endogenous CD8+ T-cells in patients with LBCL prior to CAR T-cell therapy and after CD19-directed CAR T-cell therapy.

Study objective

This exploratory study will be a proof-of-concept, open-label, single-center study to explore the feasibility of anti-CD8 PET imaging to gain insights into the biodistribution of CD8+ T-cell before and after CD19-directed CAR T-cell therapy in R/R LBCL.

Study design

D-35 until d-30 (screening), D-28 (apheresis) , D-27 until D-20 (radiation therapy o.i.), D-15 (tracer infusion), D-13 (PET), D-7 (PET), D0 (CarT infusion), D5 (tracer infusion), D7 (PET), D28 (PET), D30

Intervention

In this imaging trial, the purpose is to explore the feasibility of anti-CD8 PET imaging to gain

insights into the biodistribution of CD8+ T-cell before and after CD19-directed CAR T-cell therapy in R/R LBCL.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects with histologically confirmed LBCL and subtypes according to the WHO 2016 criteria
2. who fulfill the eligibility criteria for anti-CD19 CAR T-cell therapy according the Immune Effector Cell Working Group Tumorboard.
3. Tumor lesion(s) of which a histological biopsy can safely be obtained according to standard clinical care procedures.
4. Measurable disease, as defined by Lugano criteria.
5. Signed informed consent.
6. Age ≥18 at the time of signing informed consent.
7. Life expectancy ≥12 weeks.
8. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
9. Ability to comply with the protocol.
10. For female patients of childbearing potential and male patients with partners of childbearing potential, agreement (by patient and/or partner) to use a highly effective form(s) of contraception (i.e., one that results in a low failure rate [< 1% per year] when used consistently and correctly).

Exclusion criteria

1. Signs or symptoms of active infection within 2 weeks prior to ZED88082A/CED88004S

injection, unless treated to resolution.
2. Prior CD19-directed CAR T-cell therapy or other bi-specific antibodies targeting CD19 receptor (e.g. blinatumomab).
3. History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins.
4. Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of ZED88082A/CED88004S, or that may affect the interpretation of the results or render the patient at high risk from complications.
5. Pregnant or lactating women.
6. HIV-positive patients

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-05-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	04-11-2020
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	NL9034
Other	METc UMCG : METc 2020/559

Study results