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

Gepubliceerd: 04-11-2020 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21584

Bron
NTR

Verkorte titel
CD8 Imaging CAR T

Aandoening

Large B-cell Lymphoma

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: Genen Tech Inc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To determine the whole-body biodistribution of the ZED88082A tracer in normal tissues and tumor lesions before and after CAR T-cell therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-05-2021
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	04-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9034
Ander register	METc UMCG : METc 2020/559

Resultaten