A phase I study to investigate the safety of TEG001 cell suspension for infusion in patients with relapsed/refractory Acute Myeloid Leukemia/high-risk Myelodysplastic Syndrome (IPSS-R score >4,5) relapsed/refractory or Multiple Myeloma

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This study has been transitioned to CTIS with ID 2024-517381-42-00 check the CTIS register for the current data. This study aims to assess the safety of TEG001. Furthermore, the feasibility of TEG001 production with material from intensively pre-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON47707

Source
ToetsingOnline

Brief title
TEG001

Condition

- Haematological disorders NEC
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

blood cancer, haematological cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW beurs (NWO),Gadeta B.V.,KWF;Gadeta BV

Intervention

Keyword: &beta, &delta, &gamma, Engineered &alfa, Gene Therapy Medicinal Product, Oncology, T cells, TCR

Outcome measures

Primary outcome

Number of patients with 1 or more Dose Limiting Toxicities

Secondary outcome

1. Number of Adverse Events

2. Changes over time in quality of life

3. Feasibility of production of TEG001 cell suspension for infusion

4. Description of clinical responses

5. Levels of TEG001 in peripheral blood

Study description

Background summary

In order to further the success of immunotherapies, it is key to improve on the efficacy and applicability of a therapy and simultaneously diminish the occurrence of severe side effects. TEG001 cell suspension for infusion (TEG001 product) consists of autologous αβT cells, genetically transduced to express a specific γδT cell receptor derived from a healthy donor. The γδTCR is able to recognise various types of malignant cells. TEG therapy aims to provide a lifelong protection against malignancies, without affecting healthy tissue. In

the future, it is the aim for TEG therapy to serve as a curative treatment in various haematological and solid malignancies.

Study objective

This study has been transitioned to CTIS with ID 2024-517381-42-00 check the CTIS register for the current data.

This study aims to assess the safety of TEG001. Furthermore, the feasibility of TEG001 production with material from intensively pre-treated patients and TEG001 efficacy parameters will be assessed.

Study design

This study follows a 3+3 dose escalation design

Cohort 1: 3 Patients receive de first study dose TEG001.
(A) 0 Patients with DLT(s) -> escalate to cohort 2.
(B) 1 Patient with DLT(s) -> include another 3 patients into cohort 1, only 0 DLT(s) in these additional patients will allow to escalate to the next cohort
(C) >1 Patient with DLT(s) -> DSMB.

Cohort 2: 3 Patients receive de second study dose TEG001.
(A) 0 Patients with DLT(s) -> escalate to cohort 3.
(B) 1 Patient with DLT(s) -> include another 3 patients into cohort 2, only 0 DLT(s) in these additional patients will allow to escalate to the next cohort.
(C) >1 Patient with DLT(s) -> MTD is the dose level of the previous cohort, DSMB.

Cohort 3: 3 Patients receive de third study dose TEG001.
(A) 0 Patients with DLT(s) -> MTD has not been reached.
(B) 1 Patient with DLT(s) -> include another 3 patients into cohort 2, only 0 DLT(s) in these additional patients means the MTD has not been reached.
(C) >1 Patient with DLT(s) -> MTD is the dose level of the previous cohort, DSMB.

Intervention

The intervention consists of a single infusion of TEG001 product.

Study burden and risks

Depending on the underlying haematological malignancy, various tests will be performed in order to determine the disease status. Furthermore, cardiac, pulmonary and brain function will be assessed in order to assess if a patient is physically strong enough to undergo the conditioning chemotherapy, apheresis

and TEG001 product infusion.
Furthermore, subjects will be hospitalised for two weeks to undergo the preparative chemotherapy, TEG001 product infusion and observation.
After which regular check-ups consisting of physical examination and blood tests will be performed. Disease status will be re-assessed at day 28 and day 56 after infusion.
To mitigate any risk of this new product in this first in man study, a population was chosen with only standard of care directed towards support and symptom relief, but no therapeutic treatment options left. Pre-clinical data and the mode of action justifies the applicability of TEG001 in a broad patient population with malignancies. The potential benefit of tumour control in a patient population with an otherwise dismal outcome, outweighs the burden of the study procedures and potential side effects.

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

- Age >= 18-years
- Relapsed/refractory Acute Myeloid Leukemia/ high-risk Myelodysplastic Syndrome (IPSS-R >4.5) or relapsed/refractory Multiple Myeloma, for which no remaining standard of care or approved treatment options are available

Exclusion criteria

- In the investigators judgment, the subject is unlikely to complete all protocol-required study visits or procedures
- Other concurrent malignancy requiring treatment
- Active endogenous retrovirus
- Active GVHD and/or systemic immune suppression for GVHD
- Uncontrolled infections
- Inadequate renal, hepatic, pulmonary and cardiac function
- Pregnant or lactating women

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-07-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	07-06-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-10-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-04-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-02-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-05-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-07-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	25-02-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	19-03-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-02-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-04-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-03-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-05-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-07-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-07-2024
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

ID: 25189
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EU-CTR	CTIS2024-517381-42-00
EudraCT	EUCTR2016-003164-39-NL
CCMO	NL58686.000.16
OMON	NL-OMON25189