Safety of TEG001 in patients with r/r AML, high-risk MDS or MM

No registrations found.

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

Summary

ID

NL-OMON25189

Source
Nationaal Trial Register

Brief title
TEG001

Health condition

Acute Myeolid Leukemia (AML)

Myelodysplastic syndromes (MDS)

Multiple Myeloma (MM)

Acute Myeloïde Leukemie (AML)

Myelodysplastisch syndroom (MDS)

Multipel Myeloom (MM)

Ziekte van Kahler

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: ZonMW, KWF, Gadeta B.V.

Intervention

Outcome measures

Primary outcome

The number of patient with one or more Dose Limiting Toxicities

Secondary outcome

1. number of Adverse Events

2. description of clinical responses

3. levels of TEG001 in peripheral blood

Study description

Background summary

Background of the study:

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.

Objective of the study:

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

Study population:

Patients, aged 18-years or over, with a relapsed/refractory Acute Myeloid Leukaemia (AML)/high-risk Myelodysplastic
Syndrome (MDS) (IPSS-R>4.5) or relapsed/refractory Multiple Myeloma (MM) with only standard of care directed
towards support and symptom relief, but no therapeutic treatment options left.

Study objective

-

Study design

primary outcome: 28 days post TEG001 infusion

secondary outcomes: 56 days post TEG001 infusion

Intervention

TEG001 infusion (autologous alfa beta T cells Engineerd to express a defined Gamma delta T cell receptor)

Contacts

Public
UMC Utrecht
Anna van Muyden
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31887555878
Scientific
UMC Utrecht
Anna van Muyden
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31887555878

Eligibility criteria

Inclusion criteria

- Age ¡Ý 18-years

- Relapsed/refractory Acute Myeloid Leukemia, high-risk Myelodysplastic Syndrome (IPSS-R score >4,5) or 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

- Central Nervous System involvement of the haematological malignancy

- Other concurrent malignancy requiring treatment

- Treatment with antitumor therapy (conventional or experimental) < 28-days before start of the study treatment

- Active endogenous retrovirus

- Active GVHD and/or systemic immune suppression; < 28 days before start of the study treatment

- Uncontrolled infections

- Inadequate renal, hepatic, pulmonary and cardiac function

- Pregnant or lactating women

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):	01-06-2017
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47707
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6357
NTR-old	NTR6541

Register	ID
CCMO	NL58686.000.16
OMON	NL-OMON47707

Study results