COVID-19 vaccination in patients with reduced B-cell and T-cell immunity: response after vaccination of a kaleidoscopic group hematological patients, what’s the impact?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24355

Source
NTR

Brief title
COBRA-KAI

Health condition

Hematological Diseases

Sponsors and support

Primary sponsor: AUMC location VUmc
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

To identify subcategories of hematology patients with A) sufficient protection against COVID-19, +28 days after completion of the standard COVID-19 vaccination schedule (responders: seroconversion), B) insufficient protection, who may benefit from boostervaccinations (low-responders: antibody response but no seroconversion) and C) insufficient protection (non-responders: no seroconversion, no antibody response).

Secondary outcome

1. To characterize the humoral responses (including kinetics and persistence of antibodies, role of previous exposure to SARS-CoV2 infection) after vaccination;
2. To characterize the cellular immune response (i.e. CD4 and CD8 T-cell responses including Th1 skewing of CD4 T-cells) after COVID-19 vaccination.
3. To identify immune parameters associated with responses to COVID-19 vaccination
4. To identify clinical parameters (e.g. hematologic diagnosis, current and past therapies, date of last therapy) associated with responses to COVID-19 vaccination.
5. To monitor serious adverse events (SAE) < 7 days after each COVID-19 vaccination
6. To monitor SARS-CoV-2 infection and severity (including death) after COVID-19 vaccination

Study description

Background summary

COVID-19 vaccination response in patients with hematological disease

Study objective

Patients with hematologic conditions have a high mortality risk when infected with SARS-CoV-2. Protection from infection by vaccination is therefore of paramount importance. Many of these patients are however immunocompromised, either caused by their underlying disease, or by therapy. It is generally assumed that patients receiving (immuno-)chemotherapy or hematopoietic stem cell transplantation (HCT) for hematologic conditions will respond poorly to vaccination. However, detailed data are lacking. We hypothesize that the majority of hematology patients will acquire sufficient protection following COVID-19 vaccination, despite
disease- and/or therapy-related immunodeficiencies. Identification of non-responders is important to be able to implement additional measures for these specific patient groups.

Study design

5 times blood sampling and collecting information about COVID-19 exposure, supportive care, current therapy and WHO-PS:
- baseline (1st vaccination)
- 2nd vaccination
- 4 weeks after the vaccination

- 6 months after the vaccination
- 12 months after the vaccination

Intervention

All participants will be invited for blood sampling prior to vaccination. They will return for blood sampling prior to the 2nd vaccination and 4 weeks after completion of the COVID-19 vaccinationschedule. Since all patients are under current treatment or close follow-up, sampling at 6 and 12 months can be coupled to regular visits and blood sampling. Participants will be instructed to contact their vaccination site for any SAE within 7 days following each vaccination.

Contacts

Public
Amsterdam UMC, location AMC
Edith van Dijkman

+31641360674
Scientific
Amsterdam UMC, location AMC
Edith van Dijkman

+31641360674

Eligibility criteria

Inclusion criteria

Age ≥16 years
- The following patient cohorts will be included: Acute lymphoblastic leukemia (ALL), B-cell non Hodgkin lymphoma, multiple myeloma, chronic lymphocytic leukemia (CLL), acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), myeloproliferative diseases (MPN), patients with hemoglobinopathies (sickle cell disease and thalassemia), patients who received cell therapy (autologous HCT, allogeneic HCT or CAR T-cell therapy) AND
- Patients must either currently receive immuno-chemotherapy or have received such therapy in the past 12 months, or currently receive targeted agents, or have received autologous or allogeneic stem cell transplantation no longer than 12 months prior, or have received CART therapy.

Exclusion criteria

Unwilling or unable to give informed consent
- Known allergy to one of the components of the vaccine
- Patients with a life expectancy of < 12 months
- Of note: although we will investigate serologic evidence of prior infection with SARS-CoV-2 in all participants, seropositivity is not an exclusion criterion. The main reasons for this are first that we expect seroprevalence to be well below 5%, because of the stringent isolation measures that are already in place in this patient population; second, a test-first-strategy for seroprevalence would seriously hamper the speed of vaccination rollout, whereas vaccination of seropositive patients is indicated nonetheless, according to the national vaccination guidelines

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:	Recruitment stopped
Start date (anticipated):	01-03-2021
Enrollment:	850
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-06-2021
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	NL9553
Other	METC VUmc : 2021.0068

Study results