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?

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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…

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

Samenvatting

ID

NL-OMON24355

Bron
NTR

Verkorte titel
COBRA-KAI

Aandoening

Hematological Diseases

Ondersteuning

Primaire sponsor: AUMC location VUmc
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

COVID-19 vaccination response in patients with hematological disease

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

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 gestopt
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	850
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-06-2021
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	NL9553
Ander register	METC VUmc : 2021.0068

Resultaten