Immune response following COVID-19 vaccination in children with cancer

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PRIMARY OBJECTIVE: -To assess the antibody response after mRNA (Pfizer, Moderna) SARS-CoV-2 vaccination in children with cancer SECONDARY OBJECTIVES: To assess in children with cancer after SARS-CoV 2 vaccination: -...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON21465

Source
Nationaal Trial Register

Brief title
VACCinATE

Condition

- Viral infectious disorders

Synonym
Childhood cancer, Corona vaccination, immune response

Health condition
Childhood cancer, Corona vaccination, immune response

Research involving
Human

Sponsors and support

Primary sponsor: Princess Máxima Center for Pediatric Oncology
Source(s) of monetary or material Support: Core research funding

Intervention

Explanation

Outcome measures

Primary outcome
The primary study parameter is the antibody based immune response to vaccination against COVID-19 28 days (t=3) after the second vaccination as compared to a control cohort.

Secondary outcome
-Titers of SARS-CoV-2 specific antibodies at 12 months after the second vaccination

-SARS-CoV2 specific T cell response measured at baseline, 21-28 days after first vaccination and at 28 days after the second vaccination

Study description

Background summary
Immune responses in childrens with cancer during and shortly after end of treatment seems to be perturbed due to interference with B cell development and lack of T-cell help. This may have important consequences both on the quantity but also quality(glycosylation) of the antibody response, and thereby affect the clinical response. Therefore, in our current study proposal, we want to follow-up the effect of SARS-COV-2 vaccination in the vaccinated patients, as it is not yet clear to what extent they are able to generate both a humoral and/or cellular response against SARS-COV-2 with the regular vaccination scheme. If not, these children may need additional vaccinations to become protected.

In addition, by studying the association between the immune response with details on the disease status, treatment phase and immune-status at vaccination, this study will generate data on which rational future vaccination strategies in this patient category at great risk of infections, can be based on.

Study objective
PRIMARY OBJECTIVE:

-To assess the antibody response after mRNA (Pfizer, Moderna) SARS-CoV-2 vaccination in children with cancer

SECONDARY OBJECTIVES:

To assess in children with cancer after SARS-CoV 2 vaccination:

- durability of the antibody response

- SARS-CoV-2-specific T and B cell response

- antibody response as compared to healthy children

- the contribution of a 3rd vaccination

EXPLORATORY OBJECTIVES:

To assess in children with cancer after SARS-CoV 2 vaccination:

- the association between baseline disease and immune parameters and the immune response to SARS-CoV-2 vaccination

- the neutralizing capacity of anti-COVID-19 antibodies

- the reported incidence of SARS-CoV-2 infection and outcome of COVID-19 disease 12 months after SARS-CoV-2 vaccination

Study design
This is a prospective cohort study to evaluate the efficacy of SARS-CoV-2 vaccination in children with cancer. The study includes 4patient cohorts, which will be analysed together to answer the research questions.

Intervention
Comirnaty

Study burden and risks
There is no study-related risk. The burden is minimal. Participation in this study requires a maximum of 5 visits (cohort I) or 3 visits(cohort II, cohort III, and cohort IV) for blood draws at the hospital. Potentially eligible subjects who decide not to participate in the study will still have access to the general national SARS-CoV-2 vaccination program.

Contacts

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Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
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Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)

Inclusion criteria

- Willing to receive routine COVID-19 vaccination with Pfizer or Moderna vaccine as part of the national vaccinationprogram (cohort I)

- Having received SARS-CoV-2 vaccination with Pfizer or Moderna as part of the national vaccination program,with the last vaccination less

Exclusion criteria

- History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g. anaphylaxis) toany component of the study intervention(s).

- Not able to give informed consent (eg language problem, illiteracy)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2021
Enrollment:	130
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
None

Ethics review

Approved WMO

Date:	02-07-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 52106
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9547
CCMO	NL78187.041.21
EudraCT	2021-003388-90
OMON	NL-OMON52106

Study results

Summary results
Will follow