Vaccination against cOvid In CancEr

Published: 23-12-2020
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To assess immune response and adverse events after administration of one approved vaccine against COVID-19 in patients with cancer treated with immunotherapy and/or chemotherapy

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON52037

Source
ToetsingOnline

Brief title
VOICE

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
solid tumors

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Covid-19, Immune response, Solid tumors, Vaccination

Outcome measures

Primary outcome

The primary endpoint is the antibody based immune response to vaccination against COVID-19 on day 28 after the second vaccination in patients receiving cancer treatment as compared to individuals without cancer. Participants will be classified as responders or non-responders. The definition of response is seroconversion defined as presence of SARS-CoV-2 spike S1-specific IgG antibodies in individuals without measurable anti-S antibodies at baseline. Participants who are seropositive at baseline will not be included in the analysis of the primary endpoint. The percentage of responders of each patient cohort will be compared with the percentage responders in the group without cancer.

Secondary outcome

• Safety assessment through:

- Incidence and severity of solicited AEs during 7 days after each vaccination (see Appendix 1)

- Incidence and nature of SAEs during 7 days after each vaccination

- Incidence and nature of newly occurring irAEs [36] grade >= 3 in cohort B and D up to 28 days after the last vaccination graded according to the Common Terminology Criteria for Adverse Events version 5.0 (CTCAEv5.0)

- Incidence, nature and severity of AESIs (see Appendix 2) graded according to CTCAEv5.0

• In depth assessment of immune response through:

- Measurement of SARS-CoV2 specific antibodies before the second

vaccination to analyze initial response, and at 6 and 12 11 and 18 months after

the second vaccination to measure longevity

- Measurement of SARS-CoV2 specific antibodies at day 28 after the

third vaccination if applicable

- Assessment of SARS-CoV2 specific T cells response at 28 days after

the second and third vaccination and at 6, 11 and 18 months after the second

vaccination using a high throughput Interferon * ELIspot

Study description

Background summary

Patients with cancer have an increased risk of adverse outcome of COVID-19, which is determined by their underlying disease and/or cancer treatment. Therefore, vaccination of cancer patients against COVID-19 is recommended. However, phase III studies do not provide robust information on efficacy and safety in this vulnerable population. In patients with cancer, immunotherapy and chemotherapy may have a significant impact on the ability to develop an effective immune response to COVID-19 vaccination, and could evenalso increase the risk of adverse events.

Study objective

To assess immune response and adverse events after administration of one approved vaccine against COVID-19 in patients with cancer treated with immunotherapy and/or chemotherapy

Study design

This is an observational prospective multicentre, multicohort study.

Intervention

Vaccination with COVID-19 Vaccine Moderna

Study burden and risks

Participants will have to visit the hospital at 6 time points, and participants who receive a third vaccination will have 2 additional hospital visits. The vaccine will be administered two times according to the standard of care, with the option of a third vaccination for participants without an adequate response after 2 vaccinations. Blood will be drawn (~373 ml in total for participants receiving 2 vaccinations, and ~539 ml in participants receiving 3 vaccinations) prior to both the vaccinations and at day 28 and 6, 11 and 18 months after the second vaccination. Nasal mucosal lining fluid samples will be collected at baseline and day 28 after the second vaccination in a subgroup of patients. Blood sampling will give minor discomfort, mucosal lining fluid collection is a non-invasive procedure. The vaccine will be administered at baseline, and a booster with the interval specified by the manufacturer. Vaccination can cause adverse events including fatigue, chills, headache, myalgia, and pain at the injection site. Participants will be asked to record local and systemic reactions using a memory aid, for 7 days after each vaccination. At baseline and 3, 6 , 9, 12, 15 and 18 months after the second vaccination, patients will be asked to complete questionnaires about potential subsequent diagnosis of COVID-19, severity of COVID-19 and testing for SARS-CoV-2. Participation in this trial allows early access to vaccination.

This study will collect information on immune response and adverse events after vaccination against COVID-19 in a vulnerable patient cohort. It will also explore immune response and safety of a third vaccination in participants without an adequate antibody response after the second vaccination. Understanding the ability or disability to mount a protective immune response after vaccination will help counsel patients during the pandemic and support decisions on whom to vaccinate and to identify patients who require other measures to protect them from COVID-19. Participants will be informed aboutof their antibody titer in a letter that includes an explanation about what this means to them. This will be done after antibody measurements have been completed for day 28 after the second vaccination, and again after completion of measurements for 6 months and 28 days after third vaccination, and 11 and 18 months after the second vaccination.

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

To be eligible to participate in this study, a subject must meet all of the following criteria:
• Age of 18 years or older
• Life expectancy > 12 months
• Ability to provide informed consent

Additional criteria for cohort A:
• Partner of a participating patient

An additional criteria for cohort B:
• Histologic diagnosis of a solid malignancy
• Treatment with monotherapy immune checkpoint inhibitor (ICI) against Programmed Death 1 (PD1) or its ligand PD-L1 (in curative or non-curative setting)
• Last ICI administration within 3 months of vaccination

An additional criteria for cohort C:
• Histologic diagnosis of a solid malignancy
• Treatment with cytotoxic chemotherapy (monotherapy and combination chemotherapy is allowed, as well as a combination with radiotherapy, in curative or non-curative setting)

• Last chemotherapy administration within 4 weeks of vaccination

An additional criteria for cohort D:
• Histologic diagnosis of a solid malignancy
• Treatment with a PD1 or PD-L1 antibody in combination with cytotoxic chemotherapy (in curative or non-curative setting)
• Last chemotherapy administration within 4 weeks of vaccination
• Last ICI administration within 3 months of vaccination

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Confirmed SARS-CoV-2 infection (current or previous)
• Women who are pregnant or breastfeeding
• Active hematologic malignancy
• Immune deficiency not related to cancer or cancer treatment (e.g. inherited immune deficiency or known infection with Human Immunodeficiency Virus)
• Systemic treatment with corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medication within 14 days of vaccination. Inhaled or topical steroids, and adrenal replacement steroid > 10 mg daily prednisone equivalent are permitted. In addition, standard of care with short course steroids to prevent nausea and allergic reactions from chemotherapy or iodinated CT contrast is allowed.

Additional criteria for cohort A:
• Current or previous diagnosis of a solid tumor, unless treated with curative intent >5 years before enrolment and with no signs of recurrence during proper follow-up
• Previous history of a hematologic malignancy

An additional criteria for cohort B:
• Treatment with cytotoxic chemotherapy within 4 weeks of vaccination

An additional criteria for cohort C:
• Treatment with an ICI within 3 months of vaccination

Study design

Design

Study type:	Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2021
Enrollment:	873
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	COVID-19 Vaccine Moderna

Ethics review

Approved WMO Date:	23-12-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-03-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	03-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-09-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-09-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-01-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-01-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-06-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2021-000872-13-NL
ClinicalTrials.gov	NCT04715438
CCMO	NL76095.042.21