Efficacy of vaccine responses against SARS-Cov-2 in patients with giant cell arteritis and polymyalgia rheumatica (GPSVAC)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON51139

Source
ToetsingOnline

Brief title
GPSVAC

Condition

- Autoimmune disorders
- Viral infectious disorders
- Connective tissue disorders (excl congenital)

Synonym
Giant cell arteritis / Temporal arteritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, Giant cell arteritis, Polymyalgia rheumatica, Vaccination

Outcome measures

Primary outcome

Assessment of humoral (antibody) immune responses to the coronavirus vaccine

in GCA/PMR patients compared to the reference values and to matched healthy

controls.

Secondary outcome

Assessment of cellular (T-cell) immune responses to the coronavirus vaccine in

GCA/PMR patients

Documentation of vaccination side-effects

Study description

Background summary

Giant cell arteritis (GCA) and Polymyalgia Rheumatica (PMR) are overlapping autoinflammatory diseases that occur exclusively in people older than 50. Both diseases are treated with immunosuppressive drugs (glucocorticoids (GCs)), that suppress disease activity, but leave patients at risk for serious infections. Vaccination is thought to be the best way to prevent severe COVID-19 in these patients, however, so far no studies have been performed to assess immune responses after vaccination in GCA and PMR.

Study objective

The main objective of this study is to assess effectiveness of the COVID-19 vaccinations, based on humoral (anti-coronavirus antibody) immunity, in GCA and PMR patients. Other objectives are assessing antigen-specific cellular (T-cell)

immune responses to the vaccine, the documentation of vaccination side-effects and improving the understanding of immune responses after vaccination in GCA and PMR patients.

Study design

This is a longitudinal, observational study to investigate immune responses to vaccination. GCA/PMR patients will be asked to visit twice: pre-vaccination, and post-vaccination (28 days later). Serum/plasma and PBMCs will be stored at each visit.

Study burden and risks

As the vaccinations are part of the National vaccination programmes, the vaccinations do not present an extra burden for the participants in this study. The participants will be asked to visit the outpatient clinic twice: pre-vaccination and post-vaccination. The first corona vaccinations are planned spring 2021. If possible, the study visits will be combined with the scheduled visits as part of their regular care. Pre- and post-vaccination, six 10mL blood tubes will be drawn by venepuncture. In addition, questions will be asked with regards to infections and vaccination side-effects.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Give written informed consent
Diagnosed with GCA or PMR

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Concomitant chronic diseases that may affect the immune system (such as prior or current malignant disease, active infectious disease, other rheumatic disease, kidney disease, active allergy etc.)
Severe anaemia defined as a hemoglobin of less than 6,0 g/dL
Confirmed SARS-CoV-2 infection (current or previous)

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-05-2021

Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	COMIRNATY concentrate for dispersion for mjection
Product type:	Medicine
Brand name:	COVID-19 Vaccine AstraZeneca suspension for injection
Product type:	Medicine
Brand name:	COVID-19 Vaccine Janssen suspension for injection

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-04-2024
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	EUCTR2021-001974-52-NL
CCMO	NL77489.042.21
Other	NTR aangemeld