Immunological assessment of SARS-CoV-2 in IENIMINI cohort individuals with influenza like symptoms.

Published: 08-01-2020
Last updated: 17-01-2025

Primary objective: To evaluate, in a cohort of non-tested individuals who reported flu-like symptoms during the COVID19 epidemic in the Netherlands (March-November), the seroprevalence of COVID19 in patients with an IMID, with or without...

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

Summary

ID

NL-OMON54879

Source
ToetsingOnline

Brief title
Antibodies against SARS-CoV-2 in IENIMINI cohort individuals

Condition

- Autoimmune disorders
- Viral infectious disorders

Synonym
COVID19, infection caused by SARS-CoV-2 virus

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Target 2 B consortium (B-cel consortium)

Intervention

Keyword: antibodies, autoimmune disorder, COVID19

Outcome measures

Primary outcome

The main study parameter is the seroprevalence of COVID19 in patients with an IMID & control persons who experienced influenza like symptoms in March-November 2020.

Secondary outcome

The secondary parameter is the difference between percentage of people with antibodies against COVID19 who experienced severe symptoms versus only mild symptoms.

Study description

Background summary

The COVID19 pandemic caused by the SARS-CoV-2 virus causes enormous concerns and problems all over the world. Although the virus causes mild influenza like symptoms in the majority of the cases, some people are suffering from severe courses of the virus, often resulting in death.(7) For several groups of patients the risk of a more severe course of an infection appears to be increased, and indeed some patients may have a higher risk for falling ill after exposure than others. Patients with IMIDs might be part of these risk groups because they are more susceptible for infections than the general population.(5, 6) Their potential treatment with immunosuppressive medication might further increase this risk. To monitor possible differences in susceptibility and course of disease in SARS-CoV-2 infections between patients with IMIDs with or without immunosuppressive medication, compared to patients without IMIDs and immunosuppressive medication, the IENIMINI cohort was started in March 2020, at the beginning of the epidemic in the Netherlands. Two groups were included in this cohort, patients with an IMID with or without immunosuppressants and patients without an IMID and healthy (potential) kidney donors who served as control group. We approached patients with IMIDs from the pulmonology, rheumatology, gastroenterology and nephrology departments from the

Leiden University Medical Center (LUMC). We included patients with fibromyalgia, patients who are in follow up for familial colon cancer (Familial Adenomatous Polyposis (FAP) or Lynch syndrome) and potential healthy kidney donors in the non-IMID control group. For a complete list of included diagnoses see appendix A.

Out of 8670 patients who were approached, 3174 signed informed consent and agreed to participate in a prospective study using questionnaires to monitor potential infections, outcomes, and the relation with underlying disease and treatment. In addition, they agreed to be approached for further investigations regarding COVID19. All participants received two-monthly paper questionnaires or weekly online questionnaires where they had to register flu-like symptoms that might indicate infection with SARS-CoV-2 as they experienced them. In addition, questions about potential exposure to infected individuals, COVID19 testing, use or discontinuation of medication were completed. This prospective inventory of potential infection is currently ongoing. Preliminary results of this cohort showed 836 out of 3172 (4 patients withdrew their consent before they completed a single questionnaire) patients experienced flu-like symptoms in March-June 2020. Of these, 544 were patients with IMID and 292 were controls.

The first evaluation of the IENIMINI cohort shows us that patients with an autoimmune or autoinflammatory disorder (IMID) are not experiencing more influenza like (COVID19 like) symptoms than control persons. Also there does not seem worse outcomes for patients with an IMID. This has been confirmed by other (inter)national reports. With this study we want to evaluate what the seroprevalence is of COVID19 in patients with an IMID and control persons who experienced influenza like symptoms in March-November 2020. Besides we want to evaluate if there is a difference in immune response between participants with mild and severe symptoms.

Study objective

Primary objective:
To evaluate, in a cohort of non-tested individuals who reported flu-like symptoms during the COVID19 epidemic in the Netherlands (March-November), the seroprevalence of COVID19 in patients with an IMID, with or without immunosuppressive medication, and patients without an IMID (controls).

Secondary objective:
To evaluate the difference in antibody response to COVID19 between:
- Patients with a severe course of COVID19-like symptoms and patients with only mild symptoms.

Severe course is in this study defined as: having had fever and more than 7 executive days of illness.

Study design

This study is an observational follow-up study of the IENIMINI cohort. The IENIMINI cohort consists of two groups: patients with an IMID with or without immunosuppressants and a control group with patients without an IMID and without immunosuppressants. All patients completed questionnaires about influenza like symptoms as they experienced them in March-November 2020. After informed consent, diagnosis and prescribed medication were confirmed from their medical records. Continued use or temporary discontinuation of medication were inventoried through the questionnaires. All patients who reported an illness episode with flu-like symptoms, possibly due to COVID19 infection during March until November 2020 are eligible for this study. In conclusion, in total (2x500)= 1000 participants of the IENIMINI cohort will be asked to participate in this new study. All participants of the IENIMINI cohort have agreed to be approached for a follow up study when they gave informed consent for the IENIMINI cohort study. If a participant agrees to participate, the participant will be asked to withdraw blood by using a fingerstick test which will be send to them by Sanquin.

Study burden and risks

As this study is observational, there is no interference with standard treatment of the IMID disease. Only one assessment needs to be done. Total time investment for this follow-up study will be approximately 20 minutes. There are no immediate benefits. Patients will be informed if a SARS-CoV-2 antibody response is found, with the connotation that there is currently insufficient evidence that this is of any (lasting) benefit.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

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:
- 18 years or older
- participant of the IENIMINI cohort
- reported influenza like symptoms in March-November 2020

Exclusion criteria

No participant of the IENIMINI study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2021
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL74902.058.20

Study results

Results posted: 04-01-2022

First publication
04-01-2022