SARS-CoV-2 antibody-mediated inflammatory responses by macrophages in individuals with and without obesity

Published: 31-03-2025
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To study anti-SARS-CoV-2 antibody-mediated inflammatory responses by macrophages in individuals with obesity.

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON57369

Source
ToetsingOnline

Brief title
SAMO

Condition

- Viral infectious disorders

Synonym
coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antibodies, COVID-19, Macrophages, Obesity

Outcome measures

Primary outcome

Measurement of pro-inflammatory cytokines interleukin (IL)-6, IL-1β, and tumor necrosis factor (TNF) production by macrophages in response to SARS-CoV-2 viral and antibody costimulation.

Secondary outcome

- Pro-inflammatory cytokine (IL-6, IL-1β, and TNF) production by macrophages upon separate viral stimulation and antibody stimulation
- Macrophage expression levels of activation markers and Fc-gamma receptors
- Macrophage intracellular lipid content
- Macrophage metabolic profiling
- mRNA expression of proteins of interest in macrophages
- Epigenetic analyses: chromatin accessibility, histone modification, and transcription/epigenetic factor binding
- Proteomics (profiling of plasma proteins)
- SARS-CoV-2 antigen-specific T cell responses
- SARS-CoV-2 antigen-specific antibodies
- Clinical chemistry and haematology data (only cohort 1)
- Plasma pro-inflammatory cytokine levels
- Additional cytokines and chemokines produced by macrophages upon stimulation with antibodies

- History of and severity of prior SARS-CoV-2 infections

Study description

Background summary

COVID-19 continues to result in hospital admissions and case fatalities worldwide. Obesity is recognized as a major risk factor for severe COVID-19, yet the underlying mechanisms remain unclear. Previous studies suggest that SARS-CoV-2 antibodies may play a pathogenic role by promoting inflammation through binding to Fc-gamma receptors on alveolar macrophages. However, this mechanism has not been explored in obese individuals. A better understanding of COVID-19 pathophysiology in obese patients could lead to new therapeutic approaches, potentially beneficial for future coronaviruses that cause similar diseases.

Study objective

To study anti-SARS-CoV-2 antibody-mediated inflammatory responses by macrophages in individuals with obesity.

Study design

Prospective observational cohort study

Study burden and risks

This study aims to significantly advance our understanding of COVID-19 pathophysiology in obese patients, contributing to the broader scientific knowledge and potentially informing improved treatment and management strategies for COVID-19. These findings may ultimately benefit both individual patients and society at large. The primary risk to participants is associated with the single venipuncture, which may cause temporary discomfort or pain and carries a minor risk of hematoma formation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Cohort 1 (obesity cohort)
- >=18 and <=65 years of age
- BMI >=30 kg/m2
- Patient of Franciscus Hospital

Cohort 2 (control cohort)
- >=18 and <=65 years of age
- BMI <25 kg/m2
- Healthcare workers of Franciscus Hospital

Exclusion criteria

Cohort 1 and 2 (obesity cohort and control cohort)
- Acute infection or current systemic immunological disorders
- Use of immune-modulatory medication (i.e., corticosteroids and biologicals)
- Hormonal therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-03-2025
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	31-03-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL88800.100.25