SARS-CoV2 vaccination and activation of the coagulation system

Published: 24-03-2021
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To explore the change in circulating biomarkers of activation of the coagulation system before and after SARS-CoV2 vaccination (AstraZeneca).

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

Summary

ID

NL-OMON51038

Source
ToetsingOnline

Brief title
COCOS

Condition

- Viral infectious disorders
- Embolism and thrombosis

Synonym
covid-19, thrombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AstraZeneca, SARS-CoV2, Thromboembolic complications

Outcome measures

Primary outcome

The primary outcome is the presence of coagulation factor-inhibitor complexes

above detection levels in peripheral blood:

- TAT (Thrombin Antithrombin complex)

- Pka:C1Inhibitor

- FXIa:a1AT

- FXIa:C1 Inhibitor

- FXIa:AT

- FIXa:AT

- FVIIa:AT

Secondary outcome

Secondary parameters are:

- D-dimer and inflammatory cytokines (TNF-alpha and IL-6)

Study description

Background summary

It has been well established that increased D-dimer levels correlate with poor outcome after COVID-19 and thrombotic complications are frequent complications in patients during the acute and recovery phase of COVID-19 disease. Markers of coagulation activation are increased during Covid-19 dependent on severity. Unpublished data from our group show that ~3 months after COVID-19 infection the same complexes of coagulation factors and their inhibitors in circulating blood are still increased in 40-50% of all patients (paper in preparation). Recently, the vaccination program with SARS-CoV2 (AstraZeneca) was discontinued

in several European countries including the Netherlands because of a possible relationship with some severe cases of thrombosis combined with thrombopenia. The question arises whether SARS-CoV2 vaccination can induce activation of the coagulation system. To explore this question we propose an explorative, observational cohort study in patients undergoing SARS-Cov2 vaccination (AstraZeneca) in Groesbeek once the nationwide vaccination program continues in the Netherlands (planned March 28th).

Study objective

To explore the change in circulating biomarkers of activation of the coagulation system before and after SARS-CoV2 vaccination (AstraZeneca).

Study design

An explorative, observational cohort study including patients undergoing SARS-CoV2 vaccination (AstraZeneca). The COCOS study is initiated by and will be conducted by the Radboudumc. Participants are recruited from the general practice Paulus Potter (Groesbeek, the Netherlands).

Study burden and risks

Patients will be invited for venous blood sampling just before vaccination and 24-48 hours after vaccination at Pharmacy Groesbeek. Venous blood sampling kan cause a temporary uncomfortable sensation and/or bruising.

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:
- adult patients (age > 18 years)
- obtained written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- patients with Down syndrome
- patients with known coagulation disorders
- patients on anticoagulants (vitamin K antagonist, low-molecular weight heparin or direct oral anticoagulants)

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	24-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2021-001655-13-NL
CCMO	NL77323.091.21

Study results

Date completed:	31-05-2021
Actual enrolment:	40