Prevalence of asymptomatic deep vein thrombosis in COVID-19 patients admitted to the ward

Published: 11-06-2020
Last updated: 09-04-2024

To establish a point prevalence of asymptomatic proximal lower extremity DVT in patients admitted to the ward with COVID-19.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON49067

Source
ToetsingOnline

Brief title
DVT in COVID-19

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Pulmonary vascular disorders
- Embolism and thrombosis

Synonym
corona virus, deep vein trombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COVID-19, DVT

Outcome measures

Primary outcome

* Point prevalence of asymptomatic proximal lower extremity DVT

Secondary outcome

Parameters:

* Symptoms of lower extremity DVT (presence and duration):

o Leg swelling

o Leg pain

o Redness

* Signs of lower extremity DVT:

o Swelling of lower or upper leg as compared to the other leg

o Dilated superficial veins

o Tenderness

* Clinical course of COVID-19:

o Date of first symptoms

o Date of hospital admission

o Date of ICU admission and discharge (if applicable)

* Laboratory results (if available):

o PCR for SARS-CoV-2 (date)

o Prothrombin time, maximum during course of COVID-19 (date), latest

(date)

o Activated partial thromboplastin time, maximum during course of

COVID-19 (date), latest (date)

o D-dimer, maximum during course of COVID-19 (date), latest (date)

o Fibrinogen, minimum during course of COVID-19 (date), latest (date)

o Thrombocytes, minimum during course of COVID-19 (date), latest (date)

o C-reactive protein, maximum during course of COVID-19 (date), latest (date)

o Lymphocyte count, minimum during course of COVID-19 (date), latest (date)

* Results of compression ultrasonography:

o Date

o Presence of thrombus in common femoral vein in 3 locations, femoral vein in 1 location, and popliteal vein of both legs

* Miscellaneous data pertaining to venous thromboembolism:

o Previous venous thromboembolism (date)

o Use of anticoagulants (type, dose)

Endpoints:

* Point prevalence of symptomatic proximal lower extremity DVT

* Relationship between the presence of DVT and clinical, hematological en biochemical features

Study description

Background summary

COVID-19, the disease caused by the novel coronavirus SARS-CoV-2, is associated with coagulopathy and disseminated intravascular coagulation (REF 1,2). This may result in pulmonary embolism, especially late in the course of the illness, even despite the administration of thromboprophylaxis (REF 3).

It is unknown whether these emboli originate from asymptomatic lower extremity deep vein thrombosis (DVT). Detection of DVT in COVID-19 patients admitted to the ward before embolization to the lungs will result in treatment with therapeutic dose anticoagulants, which may prevent subsequent pulmonary embolism and resulting clinical deterioration in a patient group that is already suffering from respiratory insufficiency.

Study objective

To establish a point prevalence of asymptomatic proximal lower extremity DVT in patients admitted to the ward with COVID-19.

Study design

Observational study

Study burden and risks

Participants will be asked a small number of questions related to symptoms of lower extremity DVT, will undergo physical examination of both legs for signs of DVT and will subsequently be examined for the presence of lower extremity DVT by compression ultrasonography once. Compression ultrasonography is a routine investigation that is not harmful or associated with complications. Patients who do have DVT may experience some slight pain at the site of compression, but for most patients, even those who have DVT, the examination is painless. The result of the ultrasonography will be reported to the attending physician.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* * 18 years of age
* Admitted to a non-ICU ward
* PCR for SARS-CoV-2 positive on any sample OR diagnosed with COVID-19 on the basis of clinical, hematological, biochemical and radiological features with sufficient certainty to admit to a COVID-19 ward

Exclusion criteria

* Failure to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2020
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2020
Application type:	First submission
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	NL73930.058.20