SARS-CoV-2 Observational Study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29166

Source
Nationaal Trial Register

Brief title
SOS COVID

Health condition

acute respiratory tract infection

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: The European Commission under H2020 call SC1-PHE-CORONAVIRUS-2020

Intervention

Outcome measures

Primary outcome

The proportion of COVID-19 in patients presenting with CA-ARTI in primary care

Secondary outcome

1) The clinical presentation and management of patients with CA-ARTI by their GP in primary care during the COVID-19 pandemic and insight in differences in these aspects between

European countries
2) Risk factors for acquiring COVID-19
3) Risk factors of an adverse outcome in patients with COVID-19 in primary care
4) Self-management of patients with CA-ARTI during COVID-19 pandemic and insight in differences in these aspects between European countries

Study description

Background summary

Rationale: When a new infection emerges, most detailed information about presentation, management and clinical course is obtained from severe and/or hospitalized cases. This is currently also the case for the COVID-19 pandemic. As a consequence, little information is available from patients with mild and/or undiagnosed SARS-CoV-2 infection. These patients often contact primary care providers, either at the practice or by telephone. There is still much uncertainty about who will develop mild or more severe symptoms upon acquiring the infection and who is at risk of severe complications. We will therefore perform a study in primary care with patients presenting with acute respiratory tract infection in 4-8 European countries.

Objective: To generate information on the presentation and management of patients with community-acquired acute respiratory tract infection in primary care during the COVID-19 pandemic, to determine the proportion of these patients infected with SARS-CoV-2, and risk factors for getting COVID-19 and for a complicated course of COVID-19 disease.

Study design: Observational study with patient follow-up.

Study population: Patients aged one year and older, presenting in primary care (either in person, or phone/video), with symptoms of community-acquired acute respiratory tract infection (CA-ARTI) during the COVID-19 pandemic.

Main study parameters/endpoints: The proportion of patients with SARS-CoV-2 infection in patients presenting with CA-ARTI in primary care settings in various European countries, with description of their course of disease (illness days, non-productive days, complications and death).

Study objective

determination course of disease of COVID-19 in the primary care setting

Study design

follow-up at day 7 and 28

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

• Male or female aged one year or older;
• Consulting face-to-face, online, or telephoning with symptoms of CA-ARTI (upper and or lower), with symptoms of cough, sore throat and/or rhinitis, or when the GP has another reason to suspect COVID-19;
• Is able and willing to comply with all study requirements;
• Participant or legal guardian(s) of a child is able and willing to give informed consent;
• Availability of a freezer at the practice, patient’s home, or a laboratory location to be reached within 1 hour.

Exclusion criteria

• Patients with symptoms of earache only;
• Patients who do not master the national language or are otherwise not able to participate in follow-up procedures;
• Patients who are terminally ill;
• Patients tested positive for SARS-CoV-2 prior to recruitment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-04-2020
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	12-04-2020
Application type:	First submission

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
NTR-new	NL8520
CCMO	NL73596.041.20

Study results

Summary results
none