Corona Serology Studies in IBD Patients (COSS!P)

Published: 27-05-2020 Last updated: 09-04-2024

We aim to assess the spread of SARS-Covid2 infections by serological testing in our population of IBD-patients and describe its discourse in relation to patient characteristics, disease discourse and medication use

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Gastrointestinal inflammatory conditions

Study type Observational invasive

Summary

ID

NL-OMON49552

Source

ToetsingOnline

Brief title

COSS!P

Condition

Gastrointestinal inflammatory conditions

Synonym

IBD, inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: voor de beperkte fininaciering (kosten afname en opslag spijtserum;serologische test) moet nog een financier gevonden worden

Intervention

Keyword: Covid19, IBD, SARS-Covid2

Outcome measures

Primary outcome

Serological status for SARS-Covid 2 at regular intervals defined by the moments of routine blood sampling for the monitoring of disease activity and medication use

Secondary outcome

Short survey concerning symptoms that may be related to a SARS-Covid2 infection

Study description

Background summary

The current SARS-Covid2 pandemic poses important questions related to the treatment of patients with inflammatory bowel disease (IBD) As of jet we are not able to answer these questions because the experience with SARS-Covid2 infections in IBD-patients is sparse and relies on case reports

Study objective

We aim to assess the spread of SARS-Covid2 infections by serological testing in our population of IBD-patients and describe its discourse in relation to patient characteristics, disease discourse and medication use

Study design

This will be an observational study that applies as invasive by sequential extra blood sampling for SARS-Covid2 serological testing

Study burden and risks

participation in the study will imply the sampling of 1 extra bloodserum tube (10 ml) at moments of blood sampling that are already indicated and scheduled during routine patient care. In addition patients will be asked to fill in a

short 5 minutes survey on SARS-Covid2 related symptoms on these time points

Contacts

Public

OLVG

OLVG

Oosterpark 9 Amstredam 1091 AC NL **Scientific**

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Adult (older than 18 y) patients with inflammatory bowel disease, under care in OLVG, undergoing blood sampling for routine care

Exclusion criteria

Age below 18 years

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-04-2020

Enrollment: 2400 Type: Actual

Ethics review

Approved WMO

Date: 27-05-2020

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

ССМО

NL73853.100.20