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# Can the COVID-19 virus be detected in the smoke generated in minimally invasive surgery in patients with confirmed coronavirus infection?

**Submission date**
14/05/2020

**Recruitment status**
No longer recruiting

**Registration date**
02/07/2020

**Overall study status**
Completed

**Last Edited**
02/07/2020

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

The production of " smoke and fumes" due to the use of high energy devices in minimally invasive (laparoscopic) surgery to generate heat is well known. This smoke is composed of 95% water and 5% particles from the patient such as body cells and viruses. This represents a potential health risk due to the possibility of surgical healthcare workers contracting infectious diseases from this smoke.

Several studies have shown that laparoscopy can cause viruses that are carried in the blood to be present in these fumes, but to date, there is no evidence that this occurs with the novel coronavirus.

During the COVID-19 outbreak, despite the lack of evidence on whether the virus can be transmitted through this method, experts have advised that surgical staff take precautions to minimise the risk of this possible transmission during surgery.

This study aims to observe if SARS-CoV-2 particles can be detected in the fumes from laparoscopic surgery.

Who can participate?
Patients aged 18 to 90 years scheduled for a laparoscopic procedure at the participating hospital

What does the study involve?
Participants will have their scheduled surgical procedures. These will follow hospital and local guidelines. Additionally, participants will be required to give a blood sample prior to surgery which will be tested for COVID-19 and a Biosampler will be used during the procedure to collect particles from the fumes.

What are the possible benefits and risks of participating?
The benefits for those taking part in the study is to increase our knowledge of the possibility of transmission of the virus through the fumes generated during surgery. This has never been demonstrated but would provide evidence for an increase in safety measures to make surgery safer.

No serious adverse events are expected. If an adverse event occurs, this will be managed by the surgical team and recorded in the entries of our operating room check-list and will be communicated promptly to the investigator of the study. The event will be communicated within 5 days to the local healthcare authorities.

Where is the study run from?
Arcispedale Santa Maria Nuova (Italy)

When is the study starting and how long is it expected to run for?
From May 2020 to May 2021

Who is funding the study?
Local Health Unit of Reggio Emilia (Italy)

Who is the main contact?
1. Dr Ruggero Bollino
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# Contact information

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Public

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
600/2020/OSS/AUSLRE

## Study information

### Scientific Title
Detection of the COVID-19 virus, SARS-CoV-2, in surgical smoke during Laparoscopic Surgery (CoV2_LapSurg): a pilot investigation

### Acronym
CoV2_LapSurg

### Study objectives
SARS-CoV-2 particles will be isolated from the bioaerosol collected in solution during 20 consecutive major laparoscopic surgical procedures using the Biosampler (SKC Inc, AMS Analitica) and analysed using RT-PCR

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Approved 16/06/2020, The Ethics Committee of the Emilia Nord Vast Area (AVEN) (I.R.C.C.S - ASMN, Viale Umberto I, 50 – 42121 Reggio Emilia, Italy; +39 (0)522.296979; domenico.merlo@ausl.re.it), ref: 2020/0071828

## Study design
Single-centre prospective observational pilot study

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) detection in minimally invasive surgery

## Interventions
This is an observational trial. The study aims at analyzing with PCR the bioaerosol collected through the Biosampler (SKC Inc, AMS Analitica) in solution during 20 consecutive major laparoscopic surgical procedures to try to isolate Sars-CoV-2 particles. The presence of SARS-CoV-2 RNA in plasma of each patient will be measured before surgery using RT-PCR. There will be no follow-up of participants, all data is collected during the same surgical procedure.

The Biosampler will be connected through extension tubes to a trocar assigned to evacuate the pneumoperitoneum and to a negative pressure suction system with a flow of about 15L / min during the procedure. Surgical smoke will be collected for 30 min after major vessel exposure. The particles collected in 15 ml phosphate buffer case will then be sealed under sterile conditions and sent to the laboratory for investigation with PCR. Nucleic acid extraction will be executed by magnetic bead method on 1 ml of phosphate buffer derived by the Biosampler. A commercial One-Step Reverse Transcription Real-Time polymerase chain reaction (GeneFinder™ COVID -19 PLUS Real Real Amp Kit) will be performed in order to confirm the presence of Sars-Cov-2 in specimens by amplification of RdRp, E and N gene.

## Intervention Type
Device

## Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Biosampler (SKC Inc, AMS Analitica)

### Primary outcome measure
Correct detection of the presence of SARS-CoV-2 virus particles collected in surgical smoke during laparoscopic surgery through highly efficient Biosamplers and RT-PCR test when compared to the presence of SARS-CoV-2 RNA detected in plasma using RT-PCR in the same cohort prior to the procedure

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
23/04/2020

### Completion date
24/06/2021

## Eligibility

### Key inclusion criteria
1. Diagnosis of COVID-19 confirmed through positive RT-PCR test before surgery
2. Scheduled laparoscopic procedure at least 1.5 h duration with major vessels exposure
3. Aged 18 to 90 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
20

### Key exclusion criteria
Patients not able to give their informed consent

### Date of first enrolment
25/05/2020

### Date of final enrolment
25/05/2021

# Locations

### Countries of recruitment
Italy

### Study participating centre
**Arcispedale Santa Maria Nuova**
Azienda USL-IRCCS di Reggio Emilia
Viale Risorgimento 80
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# Sponsor information

### Organisation
Azienda Sanitaria Unità Locale di Reggio Emilia

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bonilauri.stefano@ausl.re.it

### Sponsor type
Hospital/treatment centre

### Website
http://www.asmn.re.it/

### ROR
https://ror.org/001bbwj30

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Azienda Sanitaria Unità Locale di Reggio Emilia

# Results and Publications

### Publication and dissemination plan
We planned to publish the results early after the first cases analyzed and then at the end of the study.

### Intention to publish date
01/06/2021

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Not provided at time of registration