Evaluation of COVID Prevalence, Complications and Outcome in Elective and Emergency Surgery during COVID-19-Pandemic

CovidSurgUMCG

(non-WMO study protocol)

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CONTENT

1. STUDY ORGANIZATION

Study title	CovidSurgUMCG
Planned start date	23-03-2020
Estimated completion date	**23-03-2021**
Project leader (UMCG or external)	Schelto Kruijff Surgical Oncologist Department of Surgery s.kruijff@umcg.nl
	Jean-Paul de Vries Vascular Surgeon Department of Surgery j.p.p.m.de.vries@umcg.nl
Researcher(s) UMCG	P.K.C. Jonker W.Y. van der Plas P.J. Steinkamp
Corresponding researcher UMCG	Schelto Kruijff Surgical Oncologist Department of Surgery s.k.kruijff@umcg.nl
(Principal) investigator other centers	NA
Sponsor (in Dutch: verrichter/opdrachtgever)	UMCG
Financial support/subsidising party	NA
Collaboration with non-profit Laboratory / research sites (in- and outside UMCG)	NA
Collaboration with commercial parties / companies (in- and outside UMCG)	NA
Name bio- or databank and bankmanager	NA
Name previous study ('FAIR data') and (principal) investigator	NA

2. PROTOCOL SIGNATURE SHEET

The undersigned (Principal) investigator and head of department of Surgery of the UMCG confirm that the study and its procedures will comply with the present study protocol and the nWMO Kaderreglement UMCG. Without ethical approval the data/biomaterials will not be used for other (research) purposes (e.g. 'FAIR data').

Name	Signature	Date
(Principal) investigator UMCG:	Dr. S. Kruijff, Surgeon	24-03-2020
Head of the department UMCG:	Prof. J.P.P.M. de Vries, Surgeon	24-03-2020

3. ABSTRACT

(target number <250 words)

- **Background**
  The outbreak of COVID-19 led to a global disturbance in standard surgical care with a redistribution of surgical procedures in a small time window with limited resources. There is little (inter)national evidence about the effects of the COVID-19 outbreak on potential risks for patients and the healthcare system in an acute or (semi)-elective setting. Short-term outcomes of pre- or postsurgical COVID-19 infection are currently unknown.

- **Main research question**
  What are the outcomes of surgical patients during the COVID-19 pandemic crisis undergoing elective or emergency surgery?

- **Design (including population, confounders/outcomes)**
  Design: Prospective cohort study including consecutive patients undergoing any type of elective, urgent or emergency surgery
  Primary outcome measures:
  - In hospital and 30 day mortality rate of patients with COVID-19 undergoing elective or emergency surgery.
  - In hospital and 30 day mortality rate of patients infected with COVID-19 diagnosed postoperatively during hospital admission for elective or emergency surgery.
  - Mortality of patients infected with COVID-19 30-days post-discharge following elective or emergency surgery.

Secondary outcome measures:
- Predictive parameters for mortality following elective or emergency surgery
- Prevalence of pre- and postoperative COVID-19 infection rate in patients undergoing elective or emergency surgery.
- Change of surgical strategy
- Length of ICU stay
- 7- day mortality rate
- Reoperation rate

- Morbidity rate

- **Expected results**
  We expect increased mortality and morbidity rate in COVID-19 positive patients.

4. BACKGROUND

- **Introduction and rationale**

  The outbreak of COVID-19 led to a global disturbance in standard surgical care with a redistribution of surgical procedures in a small time window with limited resources. Currenlty, there is little (inter)national evidence about the impact of the COVID-19 outbreak on surgical outcomes of patients in an acute or (semi)-elective setting. Surgical care of patients whose needs are (life) threatening, who have progessive malignancies or symptoms that need urgent care have a higher priority over non-acute patients, of which most surgeries need to be postponed in the coming weeks to months. In the UMCG, the COVID-19 outbreak is still under control with the first COVID-19 patients submitted from other hospitals to the ICU in the weekend of March 20-22. Due to the outbreak, large numbers of (semi)-elective surgery have already been postponed to relocate materials and staff. An inflow of acute and urgent surgical patients from outside this region is expected. Decisions to perform surgery in the UMCG these days is not only merely a medical decision, but more then ever a multidisciplinary decision in light of urgency, comorbidities and logistic considerations. Surgeons have to rely on international knowledge to perform triage on all patients planned for surgery during this pandemic.
  There is an urgent need to understand the outcomes of COVID-19 infected patients who undergo surgery. Real-time data will inform the management of this complex group of patients who undergo surgery throughout the COVID-19 pandemic, improving their clinical care.

  To address this aim, we will include all patients who underwent surgery at the department of surgery in the UMCG from March 14th 2020 untill the end of the outbreak of COVID-19 as determined by the World Health Organization (WHO). We will perform follow-up on 30-day mortality and morbidity rates, COVID-19-related adverse events and overall adverse event rate. After initial analysis in the UMCG we will role out this research protocol with national collaborators in multiple hospitals in the Netherlands.

- **Research question (Bank or FAIR data)**

Primary outcome measures:

- In hospital and 30 day mortality rate of patients with COVID-19 undergoing elective or emergency surgery.
- In hospital and 30 day mortality rate of patients infected with COVID-19 diagnosed postoperatively during hospital admission for elective or emergency surgery.
- Mortality of patients infected with COVID-19 30-days post-discharge following elective or emergency surgery.

Secondary outcome measures:

- Predictive parameters for mortality following elective or emergency surgery
- Prevalence of pre- and postoperative COVID-19 infection rate in patients undergoing elective or emergency surgery.
- Change of surgical strategy
- Length of ICU stay
- 7- day mortality rate
- Reoperation rate
- Morbidity rate

5. METHOD

5.1 Description study design

This is a prospective single-center observational study performed in the University Medical Center Groningen

5.2 Design

5.2.1 Mono- or multicenter study	Mono-center study yes	Multicenter study Potentially
Single-center observational study		
5.2.2 Retrospective study (available data/ biomaterials only) or prospective study (data/ biomaterials from [some] participants will be collected in the future).	Retrospective study No	Prospective study yes

5.3 Population

5.3.1 Inclusion and exclusion criteria	
• Inclusion criteria: All patients undergoing emergency or (semi)-elective surgery during the COVID-19 outbreak at the department of Surgery in the University Medical Center Groningen • Exclusion criteria: None	
5.3.2 Number of participants	
• Target total number of participants: >1000 • Target number of UMCG participants: >1000	
5.3.3 Study subjects (tick all that apply)	
• Healthy volunteers • Patients	no yes
5.3.4 Subject classification (tick all that apply)	
• Participants ≥ 16 years • Children between 12 and 16 years *(if applicable, written informed consent will be obtained from child and both parents - if both have authority, or guardian [or parents/guardian only if incapacitated child])* • Children < 12 years *(if applicable, written informed consent will be obtained from both parents - if both have authority, or guardian)*	yes yes yes

5.3.5 Incapacitated adults	
Participants are incapacitated/ decisionally incompetent adults *(if applicable, written informed consent will be obtained from legal representative)*	yes

5.4 Recruitment and informed consent/objection

5.4.2	Prospective study Patients will not sign informed consent for participation of this prospective study. In case of hospitalization after surgery during follow-up (30 days), data will be retrieved from the Electronic Patient Dossier (EPD). Follow-up will be performed every week after initial surgery (day 7, day 14, day 21 and day 30) and data will be stored in EPD and RedCap.

5.4.3 Objection (Registry)	
in case one or more participants will not be asked informed consent, the objection registry will be checked for these participants and the data from those who objected will be excluded from the analyses.	Yes
5.4.4 Informed consent (IC): access to identifiable participant data	
in case one or more study team members will have access to direct/indirect identifiable participant data, informed consent will be/has been obtained for this access.	No
All direct identifiable data will be accessible for the principal investigator and those investigators who are authorized by the principal investigator.	
5.4.5 IC: Collaboration with commercial parties	
In case of collaboration with commercial/profit organizations, informed consent will be/has been obtained for this type of collaboration	NA
5.4.6 IC: Linking with other registries	
In case the data will be linked with other registries, informed consent will be/has been obtained for this linkage(s)	NA
5.4.7 IC: Incidental findings	
In case there is a risk of incidental findings, informed consent will be/has been obtained to return findings to the participant	NA
5.4.8 IC: FAIR Data	
In case data collected for the present study will be shared for future studies, informed consent will be obtained for this	No
As these are observational data no informed consent for data sharing will be obtained.	
5.4.9 IC: other aspects	
NA	
5.4.10 Withdrawal	
• Can participants withdraw informed consent before publication and will all data/ biomaterials of that participant be destroyed • Does the participant information letter contain information on how to withdraw	No NA

5.5 Research Data Management Plan (RDMP)

In this study the data will be collected, processed, and archived in accordance with the General Data Protection Regulation (GDPR) and the FAIR (Findable, Accessible, Interoperable, Reusable) principles under the responsibility of the Principal Investigator. A research data management plan (RDMP) will be drawn up to describe the further operational details and procedures.	
√ the RDMP section below is completed ☐ a separate RDMP document will be attached to this protocol	
5.5.1 Data collection	
• Only essential baseline characteristics and data required to answer the research question(s) will be collected.	yes
Primary outcome measures: - In hospital and 30 day mortality rate of patients with COVID-19 undergoing elective or emergency surgery. - In hospital and 30 day mortality rate of patients infected with COVID-19 diagnosed postoperatively during hospital admission for elective or emergency surgery. - Mortality of patients infected with COVID-19 30-days post-discharge following elective or emergency surgery. **Secondary outcome measures:** - Predictive parameters for mortality following elective or emergency surgery - Prevalence of pre- and postoperative COVID-19 infection rate in patients undergoing elective or emergency surgery. - Change of surgical strategy - Length of ICU stay - 7- day mortality rate - Reoperation rate - Morbidity rate Parameters are attached to this application.	
• Tooling (eg. software and procedures) used for collecting, processing, analysing, and storing data will be compliant with the UMCG policy and Standard Operating Procedures in the UMCG Research Toolbox.	yes
5.5.2 Anonymization and pseudonymization	
• Data will be anonymised during data collection (i.e. data cannot be linked back to the participant)	No
• Data will be pseudonymized by use of a code list during data collection.	yes
• Indirect and direct identifiable information collected will be minimized and only collected for the purpose of this study	yes
• Direct identifiable information (e.g. contact details, code list/encryption key/subject identification log) will be stored separately from pseudonymized data <in the electronic patient files (EPD)	yes
5.5.3 Data access (during the study)	
• Direct identifiable information can only be accessed by the Principal Investigator and study delegates after authorization by the Principal Investigator.	yes

• Pseudonymized/anonymized data can only be accessed by the Principal Investigator and study delegates after authorization by the Principal Investigator.	yes
• Data roles, responsibilities, access and authorization - during the study and after study completion - will be managed and documented (e.g. in the RDMP, on study delegation log).	yes
5.5.4 Data sharing (during and after study completion)	
In case data (and biomaterials) will leave the UMCG, will you contact the loket Contract Research to arrange the proper contracts? (Loket_Contract_Research@umcg.nl)	yes
5.5.5 Data storage (during and after study completion)	
• Digital data will be archived on the UMCG network complying with strict UMCG security and back-up policy.	yes
• Paper source data and study files will be archived within the UMCG facilities.	yes
• Source data, study files and digital data will be stored 15 years after the study is completed.	yes
5.5.6 Data re-use and access after completion of the present study ('FAIR data')	NA ☐ **skip section 5.5.6**
• Data will become available and shared for re-use and participants will be asked informed consent for this ('FAIR data')	yes
• Data will be made findable by including the description of the study (and type of data (i.e. metadata) in the UMCG FAIR data catalogue and other discipline specific catalogue(s).	yes
• Review procedure, conditions and agreements for re-use of data and access to data by other researchers will be drawn up.	yes
• For this study a discipline specific metadata standard will be chosen (i.e. to increase interoperability and re-use).	no

5.6 Management of biomaterials

Will biomaterials be collected, processed, analyzed and/or stored for the purpose of this study		No **skip section 5.6**

5.7 Burden, Risks & Benefits (Prospective studies only)

• If participants are patients: Can be deviated from the standard care / diagnostic procedures (e.g. can medical treatment be postponed or limited)			no
This research does not lead to a deviation in standard of care surgery			
• Burden Follow-up by phone every week up to 30 days after surgery during the COVID-19 period. Estimated time burden per patient is 5 minutes per call.			
• Will the participants risk any injuries and/or other discomfort when they participate in the proposed study	Yes, minimal risk/burden ☐	Yes, more than minimal risk/burden ☐	No ☒
• Participant benefits/reward/incentives: There are no benefits or personal rewards for patients in this study.			

5.8 Incidental findings

• Is there a risk of incidental findings?	yes, minimal risk ☐	yes, ≥ substantial risk ☐	No ☒

5.9 Data analysis

Data will be analyzed using descriptive statistics

5.10 Participant information after the study

Will participants be informed about the study results	no
All patients undergoing surgery during the COVID-19 outbreak will receive follow-up and will not be informed about the study results personally.	

5.11 Research revenue

In case the study will result in revenues (e.g. as a result of the use of data/biomaterials or successful licensing of intellectual property or manufactured products), will you contact the loket Contract Research to arrange the proper contracts?	NA

6. REFERENCES

7. APPENDICES (if applicable)