COVID-19 and mortality in surgical patients

Submission date	Recruitment status No longer recruiting	Prospectively registered		
14/02/2024		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/06/2024	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
N8/N7/2N25	Surgery			

Plain English summary of protocol

Background and study aims

Surgical deaths may be preventable, potentially preventable or non-preventable. A preventable death is a death that should not have occurred regardless of the setting or resources whereas a potentially preventable death would not have happened if the situation was ideal. Factors that contribute to preventable or potentially preventable mortalities in surgical patients include medication errors, treatment delay, error of judgement, training issues, lack of supervision, shortage of resources and patient factors. Non-preventable deaths include deaths due to advanced cancer or severe traumatic brain injury. Around 5-15% of surgical deaths are preventable. The COVID-19 pandemic led to limitations in access to healthcare facilities and delays in the initiation of treatment. COVID-19 affects the outcomes of patients receiving surgery. Globally, it is evident that COVID-19 infection increases surgical death rates. Evidence from a recent study performed internationally illustrated that COVID-19-positive patients requiring surgery had an 18.9% risk of in-hospital mortality compared to COVID-19-negative patients where a 3.6% risk for IHM was reported. The study investigates how COVID-19 influences the preventability of surgical deaths and the contributing factors.

Who can participate?

Records of surgical patients who died during the period of study

What does the study involve?

The study involved the analysis of records of surgical patients who were admitted and died during the period of the COVID-19 pandemic from 01/03/2020 to 31/03/2020.

What are the possible benefits and risks of participating?

There were no benefits to the patients and potential risks included potential violation of privacy as the study dealt with medical records. However, data was de-identified and anonymized.

Where is the study run from?

Charlotte Maxeke Johannesburg Academic Hospital (South Africa)

When is the study starting and how long is it expected to run for? March 2020 to November 2023

Who is funding the study? Investigator initiated and funded

Who is the main contact?

Dr Thifhelimbilu Luvhengo, thifheliluvhengo@gmail.com or thifhelimbilu.luvhengo@wits.ac.za

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Thifhelimbilu Emmanuel Luvhengo

Contact details

Charlotte Maxeke Johannesburg Academic Hospital Department of Surgery Johannesburg South Africa 2193 +27 (0)839952552 thifhelimbilu.luvhengo@wits.ac.za

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

M221055 MED-09-108 HREC University of the Witwatersrand

Study information

Scientific Title

The impact of COVID-19 infection on surgical mortality in Johannesburg, South Africa

Acronym

COVID-19 Surg Mortalities

Study objectives

The study was observational. The rationale was to investigate if COVID-19 led to an increase in preventable surgical mortalities.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 24/04/2023, Human Research Ethics Committee (Medical) University of the Witwatersrand (3rd Floor, Room 306, Philip Tobias Building, Cnr York Road and Princess of Wales Terrace, Faculty of Health Sciences, Parktown, Johannesburg, 2193, South Africa; +27 (0) 117171252; Iain.Burns@wits.ac.za), ref: M221055 MED-09-108

Study design

Retrospective observational study

Primary study design

Observational

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Surgical mortality during the COVID-19 pandemic

Interventions

The study involved the analysis of records of surgical patients who were admitted and died during the period of the COVID-19 pandemic from 01/03/2020 to 31/03/2020.

Intervention Type

Other

Primary outcome(s)

The rate of occurrence of preventable mortalities among surgical patients who died during admission measured using data collected from medical records over 2 years from the 1st March 2020 to 31st March 2022

Key secondary outcome(s))

Factors that contributed to preventable surgical mortalities measured using data collected from medical records over 2 years from the 1st March 2020 to 31st March 2022

Completion date

30/11/2023

Eligibility

Key inclusion criteria

All patients who were admitted to the surgical department and died in hospital during the study period

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

404

Key exclusion criteria

Patients whose final diagnosis at death was not surgical

Date of first enrolment

25/04/2023

Date of final enrolment

01/11/2023

Locations

Countries of recruitment

South Africa

Study participating centre

Charlotte Maxeke Johannesburg Academic Hospital

Department of Surgery Johannesburg South Africa 2193

Sponsor information

Organisation

University of the Witwatersrand

ROR

https://ror.org/03rp50x72

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analyzed during the research will be made available on request with the prior permission of the local ethics committee by Thifhelimbilu Luvhengo (thifhelimbilu. luvhengo@wits.ac.za).

The type of data that will be shared: Excel spreadsheet of results.

Dates of availability: When it is requested and after obtaining permission from the local ethics committee.

Whether consent from participants was required and obtained: The study did not require consent from participants as it was an audit based on records of departmental weekly morbidity and mortality records.

Comments on data anonymization: Data was anonymized after extraction. All patient's identifiers were removed.

Any ethical or legal restrictions: Data can only be shared after receipt of ethical approval.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2025	08/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		28/02/2023	20/02/2024	No	No