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NCT number – 133196

IRAS number – 285260

### Study Title

Peri-Operative Neutrophil:Lymphocyte Ratio (NLR) as a Predictor of Outcomes Following Emergency General Surgery During the COVID-19 Pandemic

### Study Design

Observational study

### Anticipated Start Date

25/05/2020

### Sources of Funding

NIL

### Conflict of Interest

NIL

### Ethical Approval

The UK National Research Ethics Service decision tool<sup>1</sup> confirmed this study does not require ethical approval. It has been registered locally within our hospital trust Research and Development team.

### Sponsorship and Governance

An Integrated Research Application System (IRAS) form was completed (registration number 285260) and copies of the protocol submitted to Barking, Havering and Redbridge University NHST Trust (BHRUT) for sponsorship review and for Health Research Authority (HRA) approval. The protocol was subsequently submitted to clinicaltrials.gov (NCT number 133196) for registration.

### Participants/Study Population

All adult patients (>17 years) undergoing emergency (general) surgery at a single centre (Queens Hospital, Romford, UK) regardless of COVID-19 status will be included. Patients will be organised into those with:

- a) suspected or confirmed COVID-19 (diagnosed clinically, radiologically or with positive viral PCR); and
- b) those for whom COVID-19 was not suspected.

Diagnosis or suspicion of COVID-19 must be made between 7-days before and 30-days after date of surgery in accordance with the COVIDSurg study criteria<sup>2</sup>.

### Planned Study Period

Data will be collected on all patients meeting criteria undergoing emergency surgery on or after the date of UK lockdown due to COVID-19 (23th March 2020) until 22<sup>nd</sup> May 2020. If sample size is small then the end date for data collection will be extended.

### Study Questions

- 1) Is NLR a predictor of negative outcomes in patients undergoing emergency general surgery?
- 2) Is NLR different in COVID positive versus COVID negative patients undergoing emergency general surgery?

### Primary Outcome

30-day mortality

### Secondary Outcomes

7-day mortality  
Reoperation  
Length of stay  
Post-operative respiratory failure  
Post-operative ARDS  
Post-operative sepsis  
ITU/HDU admission

### Data Collection

Data will be collected using a data extraction template. This will be piloted on 5 included patients and refined as appropriate. Data will be collected from electronic sources including (but not limited to) BlueSpier, EPRO, Cyberlab and Medway. Data will include baseline patient characteristics, operation performed, COVID status and diagnostic method, NLR (pre-operative/day 0 (D0), D1, D2 and D3) and the aforementioned outcome measures. Data will be collected for 30-days following on from the date of surgery.

### Data Synthesis

For dichotomous outcome measures Relative Risk (RR) will be calculated and significance testing completed using Chi-Squared or Fisher's exact test depending on sample sizes. For continuous variables standardised mean difference (SMD) will be calculated and unpaired, two-tailed student's t-tests used for significance testing.

## References

- 1 Do I need NHS Ethics approval? <http://www.hra-decisiontools.org.uk/ethics/> (accessed 22 May2020).
- 2 Nganwa A. CovidSurg Cohort Study. Globalsurg. <https://globalsurg.org/covidsurgcohortstudy/> (accessed 22 May2020).