

TITLE (SHORT, 200 CHARACTERS MAX.):

## ORGAN DONATION FOLLOWING OOHCA

### MAIN HYPOTHESES TESTED (2 MAX)

Organ donation is a cost-effective means of treating patients with end organ failure, but there is a paucity of available organs compared to those on the transplant waiting list. In the UK Specialist Nurses in Organ Donation (SNOD) are embedded in secondary care to facilitate organ donation. In the NCEPOD 2021 report 'In Hospital Care of Out-of-Hospital Cardiac Arrests: Time Matters', organ donation was considered in 127/255 (49.8%) patients who died. In 114/124 a SNOD was involved (91.9%). When organ donation was considered it took place in 28/125 (22.4%), however the reports reviewers considered that organ donation could have been considered in another 21/122 or 17.2% of patients. Recipient outcomes from those receiving organs from OHCA donors do not appear to be different from other causes of death. Potentially there could be a substantial increase in the number of organ donors from patients dying as a consequence of OHCA. Donation can occur after brain stem death (BSD), which has been described in ~10-15% deaths or donation after cardiac death (DCD). The Step-care trial will randomise 3500 patients with an expected survival rate <50% and patients are treated according to strict withdrawal criteria that avoid early withdrawal. This will allow us to define accurately the rates of BSD

#### Hypothesis

1. There are missed opportunities for organ donation
2. We will define the incidence of BSD in this population which has previously been estimated at 10-15% in the context of avoiding early withdrawal and validate the brain death after cardiac arrest (BDCA) score (Thomas M et al Chest 160:139 (2021))

Depending on interest from other countries we will describe the infrastructure, processes and routine data capture around organ donation. We would also like to include details on statin use as this is the subject of a large RCT in the UK (Signet - Statins for Improving orGaN outcomE in Transplantation) where patients are randomized to a single dose of statin prior to organ donation.

### MULTICENTER [X]

Plan to include UK sites and other countries within the trial if interested

### PICO

Patients: All patients recruited into STEP-CARE who do not survive critical care admission.

Intervention/Exposure/Prognostic factor: Observational, all deaths in participating sites who proceed to organ donation (both DCD & DBD) to define the incidence in this population.

Observationally record the statin usage amongst non-survivors.

Comparison: Validation of the BDCA score in all participating sites, no comparative score so this is observational only.

Outcome:

Please send this form as a pdf to [josef.dankiewicz@gmail.com](mailto:josef.dankiewicz@gmail.com)

- 1) Define the number of patients with DCD and DBSD in this population to determine the incidence of missed organ donation opportunities.
- 2) Validate BDCA score in this population.
- 3) Define the usage of statins in non-survivors and the incidence of progression to organ donation in this co-hort.

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#### DATA NEEDED FOR THE ANALYSIS

(SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

The BDCA score includes - female (4 points), nonshockable rhythm (24 points), cardiac cause of OHCA (-6 points), neurological cause of OHCA (45 points), natraemia at 24 hours (natremia in millimoles per liter minus 140 points), and vasoactive drug at admission (4 points) and at 24 hours (6 points) – these are all included in the database

Additional data required:

- Statin on admission (y/n)
  - o if yes, statin continued during ICU admission (y/n)
    - if yes, statin name
    - if yes, statin dose
- Statin commenced during ICU admission (y/n)
  - o if yes, statin name
  - o if yes, statin dose
- Death confirmed using neurological criteria (brain death) (y/n)
- For **all non-survivors**: Organ donation approached?
  - o If yes, (for all non-survivors where organ donation approached): Organ donation accepted / declined by family (y/n)
    - If yes, (for all non-survivors where organ donation accepted by families): Organ donation accepted / declined by transplant centres (y/n)
- Time / date of withdrawal of life sustaining therapy

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#### LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

In the UK much of the required data will be recorded as part of the organ donation process – donation considered, SNOD involved, consent declined, number of organs transplanted etc., We will explore processes in other countries to see if additional data needs to be added to the database

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#### BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

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#### FUNDING (IF APPLICABLE)

None at present, however organ donation in the UK is administered through NHSBT (NHS Blood and Transplant) which employs SNODs and Clinical Leads for Organ Donation (CLOD). This sub-study may identify a shortfall in potential organs for transplantation and possibly identify BSD at an earlier stage which would be in the interest of NHSBT. We will approach the lead for organ donation at NHSBT to see if it is possible to award a small site fee for participation.

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CO-WORKERS:

To be included according to interest from participating countries sites