EVIS PROTOCOL

NCT05179499

SCHEDULE OF ASSESSMENTS

Trial Activity	Screening	Baseline	6 hours (+/- 1 hour)	12 hours (+/- 4 hours)	24 hours (+/-6 hours)	48 hours (+/-12 hours)	72 hours (+/-12 hours)	+/- 7 days	Hospital Discharge	30 Days Mortality check	30 days (QOL) +/- 7 days)	90 Days Mortal ity check	90 days QOL)
Eligibility –	Х	Х											
Inclusion/Exclusion*/**													
Pregnancy test **		Х											
Written Informed Consent	Х												
Demographics/Medical History/estimated weight/ Frailty score		Х											
Vital signs *		Х	Х	Х	X	Х	X						
Blood results (routine) incl lactate		X***	X****	X****	X****	X****	X****	X****					
IMP administration		Х	Х	Х	X	Х							
IMP adherence		Х			X	Х							
Total intravenous fluid volume delivered		Х	×	Х	X	X	X						

EVIS PROTOCOL

NCT05179499

Total dose of	Х	Х	Х	Х	Х	Х						
norepinephrine delivered												
Total dose of other	Х	Х	Х	Х	Х	Х						
vasopressors delivered												
Safety outcomes						Х		Х				
(pulmonary												
oedema/extravasation)												
Mortality/interventions/le								Х	Х		Х	
ngth of												
stay/readmissions												
****/****												
Adverse Events ******	Х	Х	Х	Х	Х	X**	Х					
EQ-5D-5L *******	Х									Х		Х

* Once eligibility has been determined by the medical Investigator and the patient confirmed eligible, sites should proceed to randomisation as soon as practical. Due to the emergency nature of EVIS, it is noted the patient's vital signs and intake of intravenous fluids may fluctuate however it is those vital signs and intravenous fluids reviewed at the time of eligibility that determine entry into the trial.

** All women of childbearing potential must have a negative urine or serum pregnancy test completed as part of study eligibility checks.

*** A serum lactate must be measured for eligibility. The serum lactate should be measured 2 hours prior to determination of eligibility, where possible. Longer timeframes may be used and justified within the medical notes if, in the opinion of the investigator, the clinical status of the

EVIS PROTOCOL

NCT05179499

patient has not significantly improved in the time interval between lactate measurement and eligibility assessment. Lactate measurements more than 4 hours prior to eligibility assessment should not normally be used.

**** Daily (+/- 12 hours) for any routine bloods collected up to 72 hours.

***** All-cause mortality at day 30 is a primary outcome. The mortality check should be performed on days 31-44 by reviewing the participant's medical records. The assessment **must** reflect the participant's status on day 30. Protocol deviations will be recorded where the review is completed out with this window, including day 30, unless the patient is already deceased.

****** 90 day mortality should be performed on days 91-105 by reviewing the participants' medical records. The assessment **must** reflect the participant's status on day 90. Protocol deviations will be recorded where the review is completed out with this window, including day 90, unless the patient is already deceased.

****** Adverse Event reporting is a continuous process

******** EQ-5D-5L should only be completed if the patient has capacity.

Please note if bloods (or individual parameters) are not requested by the clinical team, this will not be recorded as a deviation unless it affects the eligibility of the patient.