

EVIS: Information Sheet for Clinical Staff: CONTROL Arm



Study: EVIS: Early Vasopressors in Sepsis (EudraCT No: 2021-006886-39)

EVIS
Participant No.:

Randomisation:

This patient has been randomised to the **USUAL/STANDARD CARE arm** of the EVIS study.

Insert Patient ID/Addressograph label

Participant randomised on:

_____ (insert date) at _____ (insert time hh:mm)

If you need more information:

- Contact the Research Team on _____
- The protocol and other current study documents can be found on the website www.evis.scot.nhs.uk or by scanning the QRS code opposite



Key information for CLINICIANS for USUAL CARE (CONTROL) arm

Randomisation: USUAL CARE (Control) arm

Study treatment period: maximum 48 hours from time of randomisation. See above.

The following tasks can ONLY be performed by trained research staff on the site delegation log:

- Initial prescription of balanced crystalloid IV fluids

Initial treatment (3 hours post-randomisation)

- Administer up to 30ml/kg balanced crystalloid intravenous fluid for fluid resuscitation.
- Titrate intravenous fluid administration to target MAP of 65 mmHg.
- Permitted balanced crystalloid IV fluids (any brand)
 - Compound sodium lactate (Ringers Lactate or Hartmanns solution)
 - Plasma-lyte 148

Anticipated most participants will receive up to approximately 30ml/kg in the first 3 hours using 250-1000ml rapid infusion (bolus) of balanced crystalloid for fluid resuscitation.

Ongoing treatment (up to 45 hours post-randomisation)

- Further balanced crystalloid boluses for resuscitation is at discretion of clinical team.
- Titrate intravenous fluid administration to target MAP of 65 mmHg.

Maintenance and rescue treatment that may be prescribed by the treating clinician

- **Rescue vasopressors:** Rescue vasopressor of clinician choice via CENTRAL line. Participants must not receive any peripheral vasopressor infusion during the 48 hour study period even where peripheral administration is accepted practice at site.
- **Maintenance intravenous fluids:** Defined as any fluid at a rate of ≤ 125 ml/hour
- **Requirement for operative intervention:** Maintain treatment allocation where possible. Anaesthetist discretion permitted for other fluids, blood product and vasopressor use.
- **End of study period (> 48 hours since randomisation):** Treatment may continue as per standard care once the EVIS study period is completed.

Other treatment: As per UK national guidelines/local protocols on sepsis.