PRESSURE Trial
Screening & enrolment flowchart
For patients identified by the site research teams

If your site is also participating in Oxy-PICU, consider patients on vasoactive drugs for enrolment to PRESSURE only after checking they were not previously enrolled into Oxy-PICU.

Co-enrolment with Oxy-PICU is not permitted.

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Is the patient accepted for or admitted to PICU and on vasoactive drugs?

Yes → Consider screening for eligibility

No → Do not consider for PRESSURE

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Consider screening for eligibility

SOP 003

Does the patient meet all inclusion criteria and no exclusion criteria?

Yes → Contact appropriately trained staff member from the site team to confirm eligibility

No → Do not randomise patient into the trial

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Contact appropriately trained staff member from the site team to confirm eligibility

SOP 004

Appropriately trained staff member must randomise the patient into the trial ASAP, but no longer than 6 hours from initiation of vasoactive drugs.

Complete the randomisation form (hard copy) for each patient and record the randomisation details as generated by the randomisation system.

Appropriately trained staff member must sign off the randomisation form

SOP 006

SOP 005

Deliver the intervention the patient has been allocated to and follow the consent procedures, as per the latest version of the protocol.

Site research team must record the details from the randomisation form into the screening & enrolment log and retain the randomisation form in the ISF.

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Site research team may complete the first section of the randomisation form (hard copy), although this is optional.

Site research team must complete the screening & enrolment log.

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If patient is put on vasoactive drugs later during PICU stay, site research team should re-screen.