

## Place in Site Master File #9a iii

#### **Trial medication**

### IV fluid restriction group

NO IV fluids unless:

- 1) In case of **severe hypoperfusion** or severe circulatory impairment:
  - → Lactate ≥4 mmol/L
  - → MAP <50 mmHg (+/- vasopressor/inotrope)</p>
  - → Mottling beyond edge of kneecap (mottling score>2)
  - → Urinary output <0.1mL/kg body weight/h (only first 2 hrs after randomisation)

IV fluid bolus (250-500mL) may be given (not mandated) followed by re-evaluation

In case of <u>overt fluid losses</u>
(e.g. vomiting, large aspirates, diarrhoea, drain losses, bleeding or ascites tap)

IV fluids may be given to correct for the loss only

3) In case the <u>enteral route has failed</u> (or is contraindicated)

IV fluids may be given to:

- → Correct dehydration or electrolyte deficiencies
- → Ensure a total fluid input of 1L per 24h (incl. all fluids with medication and nutrition)



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#### **Standard care group**

No upper limit for the use of either IV or enteral fluids. IV fluids should be given:

- 1) In case of hypoperfusion and continued as long as hemodynamic variables (as chosen by clinicians) improve<sup>1</sup>
- 2) As maintenance if the ICU has a protocol recommending so
- To substitute expected or observed loss, dehydration or electrolyte derangements