FAQs for Recruiting Sites

Clinical

1. What dosing guidelines should we use? Is there any guidance?

All sites should follow their local guidance for dosing. For units that do not have written guidance, we have provided dosage and administration guidance in the protocol.

2. Will BASE supply the Investigational Medicinal Product (IMP)?

Hospital stock of sodium bicarbonate will be used. There will be no over-labelling of the IMP, nor any pharmacy or accountability files.

3. Are they any allowed uses of intravenous sodium bicarbonate?

The use of intravenous sodium bicarbonate is allowed in any of the following circumstances for either arm. This is not an exhaustive list:

- Use as a substitute for normal saline in arterial line infusion
- Use during cardiopulmonary resuscitation
- Severe acidaemia and continued clinical deterioration despite escalating intensive care management and supportive treatment with volume cardiovascular support and antibiotic therapy with a persistently low pH below 7.1
- Nephrologist diagnosis of renal tubular acidosis
- Confirmed diagnosis of an underlying inborn error of metabolism made after randomisation
- Chronic renal failure

4. Can alternative methods to treat metabolic acidosis be used?

It is expected that clinicians will treat the underlying cause of metabolic acidosis, if present. Use of THAM in either arm is discouraged. However, if administered this should be recorded in Table 1 of the dosing log. If the unit practice is to use parenteral nutrition containing acetate, this too should be recorded in the dosing log.

5. Who can administer sodium bicarbonate?

The administration of the IMP is dependent on local policy and procedure, there are no study specific requirements. Anyone who would usually administer sodium bicarbonate can do so.