Study Intervention

Please ensure your site always has a sufficient hospital stock of Sodium Bicarbonate for the duration of the study.

The infant can be randomised to either:

1. **Routine use of sodium bicarbonate infusion for episodes of metabolic acidosis (Intervention)**

2. **No routine use of sodium bicarbonate infusion for episodes of metabolic acidosis (Control)**

Investigational Medicinal Product (IMP)

As an open-label trial comparing standard care pathways, the trial will use **Neonatal Intensive Care Unit (NICU) stock of sodium bicarbonate** for intravenous infusion.

Storage, accountability and destruction of sodium bicarbonate will be as for standard clinical care according to NHS hospital policy.

We therefore do not require trial accountability logs to be completed.

Dosage

Dosage and duration of infusion will be decided by the treating clinician. All other aspects of care will also be determined by the treating clinician.

For units that do not have a written guideline, dosage and administration is provided below.

To calculate the dose of sodium bicarbonate, use the following formula. The dosage to correct the base deficit is at the discretion of the treating clinician.

Mmol of $NaHCO_3$ = (0.3 to 0.6) x weight (kg) x base deficit (mmol/L)

The rate of the infusion depends on the clinical situation. Acceptable duration of infusion ranges from 30 minutes to 4 hours.

8.4% sodium bicarbonate injection contains 1 mmol/ml.

Prepare infusions for corrections by diluting 4.2% sodium bicarbonate with equivalent volume of water for injection.

Provision of sodium bicarbonate beyond the trial period will only take place as part of ongoing clinical management.

GUIDANCE SHEET

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Adherence

Adherence to the allocated care pathway will be recorded in the **Daily Dosing Log** by recording the date and time of episodes of metabolic acidosis and the use of sodium bicarbonate.

Allowed uses of intravenous sodium bicarbonate

The use of oral sodium bicarbonate, and sodium bicarbonate infusion for the following clinical reasons will not be considered non-adherent:

- 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

Uses outside of the trial indication for circumstances other than these will be reviewed.

Please try to adhere as closely as possible to a baby's allocated pathway throughout the trial period.

For more information on adherence, please see section 10.4 of the BASE Protocol.

GUIDANCE SHEET