

Randomisation Form (page 1 of 2)



Patient details (local use only)

Initials: Hospital Number: Unit:

To randomise an eligible patient, log on to: <https://sealedenvelope.com/access>



Web randomisation (continued overleaf)

Eligibility

Inclusion criteria

Age (years): *Must be ≥18 years*

Metabolic acidosis:

Arterial Blood Gas values *Must be from same ABG, most recent prior to randomisation*

pH: . *Must be <7.30*

PaCO₂: . kPa *Must be <6.5 kPa*

Please remember the following:

Depending on local policy Sodium Bicarbonate 8.4% may need to be administered centrally, in which case patients should have or be planned to have central line access

AKI KDIGO stage 2 or 3*:

Serum creatinine (sCr)

Baseline sCr[†]: μmol/L

Tick box if estimated OR Enter date of Baseline creatinine DDMMYY

Must be within 365 days prior to current hospital admission. See guidance below.

sCr at randomisation: μmol/L

→ If ≥354 μmol/L and <1.5 times baseline sCr, was AKI diagnosed using a rise of ≥27 μmol/L within 48 hours? Yes No

Urine output

Urine output of <0.5 ml/kg/h for ≥12 hours? Yes No

Definitions

*AKI KDIGO stage 2 or 3 is defined as any one of the following three criteria:

- Serum creatinine ≥2.0 times baseline[†]
or
- Serum creatinine ≥354 μmol/L, AND
either a rise of ≥27 μmol/L within 48 hours or serum creatinine ≥1.5 times baseline[†]
or
- Urine output of <0.5 ml/kg/h for ≥12 hours

[†]For baseline serum creatinine value:

- If available, then use pre-hospitalisation value within 365 days of the current hospital admission date.
- If there are multiple pre-hospitalisation values, then use the one closest to the date of the current hospital admission.
- If a pre-hospitalisation value from the 365 days prior to admission date is not available and there are multiple serum creatinine values from the current hospitalisation, then use the lowest one from the current hospitalisation.
- If no baseline serum creatinine value is available, then estimate it using the provided calculator.

Randomisation Form (page 2 of 2)



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Web randomisation (continued)

Exclusion criteria (all must be No)

Acute or chronic respiratory acidosis	Yes <input type="radio"/> Y	No <input type="radio"/> N	
KRT planned to start in the next 3 hours and treating clinician(s) unwilling to defer if randomised to sodium bicarbonate	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Deemed unsuitable for KRT	Yes <input type="radio"/> Y	No <input type="radio"/> N	
High output stoma/ileostomy	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Percutaneous biliary drainage	Yes <input type="radio"/> Y	No <input type="radio"/> N	
End stage kidney failure defined as documented eGFR < 15 ml/min/1.73m ² prior to onset of this acute illness or ESKD on dialysis	Yes <input type="radio"/> Y	No <input type="radio"/> N	Baseline eGFR (if available): <input type="text"/> <input type="text"/> <input type="text"/> ml/min/1.73m ² Must be ≥15 to be eligible
Known renal tubular acidosis	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Diabetic ketoacidosis	Yes <input type="radio"/> Y	No <input type="radio"/> N	
High anion gap acid poisoning (e.g. PEG, aspirin, methanol)	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Symptomatic hypocalcaemia (Ionised calcium < 1.05 mmol/L)	Yes <input type="radio"/> Y	No <input type="radio"/> N	Ionised calcium: <input type="text"/> . <input type="text"/> mmol/L If < 1.05, is hypocalcaemia symptomatic? Yes <input type="radio"/> Y No <input type="radio"/> N
Hypernatraemia (Plasma sodium > 150 mmol/L)	Yes <input type="radio"/> Y	No <input type="radio"/> N	Sodium: <input type="text"/> <input type="text"/> <input type="text"/> mmol/L Must be ≤150 to be eligible
Severe hypokalaemia (Potassium < 3.0 mmol/L)	Yes <input type="radio"/> Y	No <input type="radio"/> N	Potassium: <input type="text"/> . <input type="text"/> mmol/L Must be ≥3.0 to be eligible
Death perceived as imminent	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Known hypersensitivity to sodium bicarbonate or to any excipients listed in section 6.1 of the SmPC	Yes <input type="radio"/> Y	No <input type="radio"/> N	
Previously randomised into MOSAICC	Yes <input type="radio"/> Y	No <input type="radio"/> N	

Arterial Blood Gas values
Use most recent ABG prior to randomisation for all values (all from same ABG)

Randomisation confirmation

Treatment allocation: S Sodium bicarbonate (intravenous 8.4% weight by volume) N No sodium bicarbonate

Date/Time of randomisation: / / 2 0 2 Y : (24-hour clock) Trial ID:

Randomised by: Signature:

Eligibility confirmed by (if different to above): Medical oversight provided by Dr (if different to above):

MOSAICC Randomisation Form v3.2, 20NOV2024 Store completed form in Investigator Site File and document randomisation in patient notes