

Treatment of Hyperkalaemia in an Emergency with Lokelma, an oral Potassium binder; the design and rationale for the HELP-K randomised placebo-controlled trial

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Background:

Hyperkalaemia is a common and serious medical emergency present in up to 10% of medical admissions. Current standard of care consists of an insulin/dextrose infusion (IDex), but this treatment has important limitations including the need for re-treatment due to its transient hypoklaemic effect, risk of hypoglycaemia, and requirement for hospitalisation.

Sodium zirconium cyclosilicate (SZC, Lokelma) is an oral agent that lowers serum potassium by rapidly binding potassium throughout the gastrointestinal tract. It is licensed for use in both the United States and the European Union for the treatment of hyperkalaemia. To date, no randomised trial data has been published describing a role for SZC in the emergency management of hyperkalaemia.

Methods:

HELP-K is a randomised, double-blind, placebo-controlled, trial of SZC for the emergency treatment of hyperkalaemia in addition to standard of care. 194 patients aged 18 years or older with a serum potassium \geq 5.8 mmol/L will be enrolled at 15-20 sites in the United Kingdom and randomly allocated to either SZC or placebo in addition to IDex. Patients with End-Stage Kidney Disease, diabetic keto-acidosis or pregnancy will be excluded.

Participants will receive six doses of SZC or placebo over 48 hours in addition to standard care during the acute presentation. During a maintenance phase, participants will receive once daily SZC or placebo, titrated to serum potassium concentration, for a total of six weeks. Following discharge from hospital, patients will be assessed at 21 and 42 days. The primary outcome is time-to-treatment failure. Treatment failure is defined as re-treatment with IDex or use of renal replacement therapy for hyperkalaemia. Secondary outcomes include evaluating the addition of SZC to IDex on adverse events (such as hypoglycaemia) and whether the addition of SZC enhances serum potassium reduction and helps to facilitate earlier discharge from hospital.

Results:

Recruitment is expected to commence in Spring 2020. There are no results to present.

Conclusion:

There is a clear unmet need for improved, evidence based emergency treatments for hyperkalaemia. Data exists to suggest that the rate of potassium lowering with SZC is sufficiently rapid to have utility in this setting. HELP-K will determine if SZC has the potential to reduce exposure to IDex and to improve the safety of hyperkalaemia management.