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Feasibility of Embedding a Randomised Clinical Trial (RCT) into an Electronic Medical Record (EMR) for Patients Admitted to an Intensive Care Unit (ICU)

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Abstract. To establish the feasibility of embedding an RCT into EMR in the ICU, we evaluated the route of phosphate replacement. The EMR screened 207 patients who met the inclusion criteria from 20 April 2022 to 30 June 2022. 162 patients were randomised and 145 patients allocated to treatment. Our study showed that it was feasible to embed screening, randomisation, and treatment allocation for an RCT within an EMR in the ICU.

Keywords. Critical Illness, Epic, Electronic Medical Record, Intensive Care Unit, Randomised Clinical Trial

1. Introduction

To establish the feasibility of embedding an RCT into an EMR in the ICU, we evaluated the route of phosphate replacement. We chose phosphate replacement as a model for emergency interventions that could be studied because hypophosphatemia occurs frequently, and the majority of patients receive intravenous phosphate replacement [1]. We hypothesised that phosphate replacement via the enteral route would be non-inferior to intravenous phosphate to treat hypophosphatemia in critically ill patients but would have 'down-stream' benefits as it would be cheaper and cause less healthcare waste.

2. Methods

We conducted a single-centre, prospective, open-label, parallel-group, randomised, non-inferiority trial. We randomised patients with serum phosphate concentration between 0.3 and 0.75 mmol/L to either enteral or intravenous (IV) phosphate replacement while in ICU and censored at 7 days. Our primary outcome was serum phosphate concentration at 24 hours after enrolment with a non-inferiority margin set at 0.2 mmol/L. Secondary outcomes included the number of replacement phosphate doses administered, daily serum phosphate concentrations, the incidence of severe hypophosphatemia (< 0.3 mmol/L) and cost-effective and environmental waste analysis. Data are mean (SD) or

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median [Q1-Q3]. We defined usual office hours as between 0800- and 1800-hours Monday to Friday when a research coordinator would have been available for screening and enrolment. Our protocol was approved by the research ethics committee with a waiver of consent.

3. Results

From 20 April 2022 to 30 June 2022, the EMR identified 207 patients who met the inclusion criteria, with 45 meeting at least one exclusion criterion. Within the EMR, 162 patients were randomised, with the clinician then informed of allocation with a 'Best Practice Alert' as to the route that of phosphate replacement. Clinicians chose to ignore the Best Practice Alert for 17 (10%) patients and 145 patients had the prescription signed consistent with study allocation. Therefore, over 71 days, we enrolled 145 patients with a serum phosphate of 0.3 to 0.75 mmol/L. Enrolment occurred during usual office hours in 29 of 145 (20%) patients with the rest occurring outside of this period.

Of the 145 trial patients, 66 were allocated to enteral and 79 allocated to intravenous replacement. Twelve patients did not have serum phosphate concentrations subsequently measured and were excluded from the analysis. Preliminary results show that baseline phosphate concentrations were similar (enteral 0.57 (0.11) vs. IV 0.60 (0.11) mmol/L). At 24 hours, serum phosphate concentrations were similar to enteral replacement (0.89 (0.24) vs. 0.83 (0.27) mmol/L). There was no difference in phosphate concentrations over time. Two patients both receiving intravenous developed severe hypophosphatemia. Enteral replacement of phosphate cost $1/10^{th}$ and lead to $1/30^{th}$ the healthcare waste when compared to intravenous replacement

4. Conclusions

It was feasible to embed screening, randomisation and treatment allocation for an RCT within an electronic medical record (EMR, Epic) in the ICU, with most enrolments occurring outside of usual office hours when a research coordinator was not available. Using phosphate replacement as a model, we found that enteral phosphate replacement in ICU is not inferior to intravenous replacement at a margin of 0.2 mmol/L but was more cost-effective with less environmental impact than intravenous replacement.

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