

Efficacy of skimmed milk administration in mild and moderate hypophosphatemia (SMPhos): An open-label randomized controlled clinical trial

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Currently, there are no commercially available phosphate tablets or intravenous preparations for correction of hypophosphatemia in the Philippines. Hence, a non-inferiority, open-label, randomized controlled pilot trial was performed at Makati Medical Center, a tertiary hospital in the Philippines. The study aimed to compare skimmed milk with the institutionally accepted formulary phosphate buffer solutions in raising serum phosphorus levels in patients with mild and moderate hypophosphatemia. A total of 41 participants were randomized. Participants randomized to skimmed milk (n = 20) were given a total of 150mL/day divided into three doses while those randomized to phosphate solution (n = 21) were given 60mL in 3-6 divided doses. Treatment difference was determined using the mean percent change between skimmed milk and phosphate solution, with the non-inferiority limit that we set at 15%. The frequency of adverse events was noted, and intention to treat was done.

Results: Study showed that skimmed milk was able to raise serum phosphorus levels post-treatment but was not significantly different from phosphate solution (2.62 ± 0.76 mg/dl vs. 3.02 ± 0.94 , $p = 0.14$). The mean percent change was higher in the phosphate solution group ($50.32\% \pm 44.4$) than skimmed milk ($30.93\% \pm 32.3$) but was not statistically significant ($p = 0.12$). The mean percent change difference between the two treatments is -19.39% (95% CI: $-44.5, 5.47$). There were no adverse events noted with skimmed milk, but there was an isolated episode of abdominal pain and vomiting with phosphate solution. Intention to treat analysis was done. The key finding of our trial is that giving skimmed milk was not different from phosphate solutions in raising serum phosphorus levels in mild or moderate hypophosphatemia. Although, statistically significant non-inferiority was not met. Nevertheless, skimmed milk is still a safe, readily available, and inexpensive alternative for phosphorus correction in resource-limited areas.