This study is a retrospective review of inpatient administration deviation reports for an investigational drug that is administered daily with infusion times of 8-24 hours, and variable treatment durations for each patient" Fell et al (2016).

Abstract:

There are few evidence-based guidelines to inform optimal design of complex clinical trials, such as those assessing the safety and efficacy of intravenous drugs administered daily with infusion times over many hours per day and treatment durations that may span years. This study is a retrospective review of inpatient administration deviation reports for an investigational drug that is administered daily with infusion times of 8-24 hours, and variable treatment durations for each patient.

We report study design modifications made in 2007-2008 aimed at minimizing deviations from an investigational drug infusion protocol approved by an institutional review board and the United States Food and Drug Administration. Modifications were specifically aimed at minimizing errors of infusion rate, incorrect dose, incorrect patient, or wrong drug administered. We found that the rate of these types of administration errors of the study drug was significantly decreased following adoption of the specific study design changes. This report provides guidance in the design of clinical trials testing the safety and efficacy of study drugs administered via intravenous infusion in an inpatient setting so as to minimize drug administration protocol deviations and optimize patient safety.

Reference:

Fell, G.L., O'Loughlin, A.A., Nandivada, P., Potemkin, A.K., Mitchell, P.D., Mahoney, J., Gura, K.M. and Puder, M. (2016) Methods to Reduce Medication Errors in a Clinical Trial of an Investigational Parenteral Medication. Contemporary Clinical Trials Communications. 4, p.64-67.

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