Study Title: Development of Infusion Monitoring System to Prevent Phlebitis, Infiltration and Extravasation and Its Application in Intensive Care Unit

Introduction

This study was planned to evaluate the effectiveness of the infusion monitoring system created to prevent complications that may develop frequently during or after drug infusion in clinics. The study aims to reduce the incidence of phlebitis, infiltration and extravasation in Ordu State Hospital General Intensive Care 1 and General Intensive Care 3 clinics. These two clinics have similar patient profiles and treatment plans are carried out by the same physicians. In the first stage of the study, the infusion tracking system will be designed and the software will be created. Then, the infusion monitoring system will be used by the nurses and its effectiveness will be evaluated. The nurses in the clinic in the control group will follow their routine procedures in patient care.

Method

Aim and type of the study

The aim of this study was to create an infusion monitoring system and evaluate its effectiveness in the early detection of peripheral intravenous catheter-related complications. The study was planned as a randomised controlled experimental study.

Research Hypotheses

H_{01}: Infusion monitoring system has no effect on the prevention of phlebitis among peripheral intravenous catheter-related complications.

H_{11}: Infusion monitoring system has no effect on the prevention of phlebitis among peripheral intravenous catheter-related complications.

H_{02}: The infusion monitoring system has no effect on the prevention of infiltration, one of the complications associated with peripheral intravenous catheters.

H_{12}: The infusion monitoring system is effective in preventing infiltration, one of the complications associated with peripheral intravenous catheters.

H_{03}: The infusion monitoring system has no effect on the prevention of extravasation, one of the complications associated with peripheral intravenous catheters.

H_{13}: The infusion monitoring system is effective in preventing extravasation, one of the complications associated with peripheral intravenous catheters.

Population and Sample of the Study

The population of the study will consist of two intensive care units. The final sample size will be determined by a G*Power analysis following a two-month pilot observation period. A preliminary sample size estimation was conducted before initiating the study. Based on a 95% confidence level (1-α), a 5% margin of error, and an incidence rate of 10.68%, the minimum required number of cases to be included in the study was determined to be 102. The validity and reliability of the infusion monitoring system developed for this study will also be tested.

Inclusion criteria: Patients aged 18 and above, receiving medication through a peripheral intravenous catheter, monitored daily for signs of phlebitis, infiltration, and extravasation, and who are conscious and able to respond, will be included in the study.

Exclusion criteria: Patients who are unconscious and unable to respond will be excluded from the study.

Data Collection and Instruments

Data Collection Forms

The data will be collected using the following forms developed by the researcher through literature review:

- Clinical Monitoring Form
- Patient Information Form
- Complication Monitoring Form
- Peripheral Edema Scale
- Glasgow Coma Scale

Application Tools

Development of the Infusion Monitoring System
The infusion monitoring system software will be developed as a technological tool to improve

nurses' peripheral infusion monitoring skills, increase awareness, and reduce the incidence of peripheral venous catheter complications such as phlebitis, infiltration, and extravasation.

Implementation and Data Collection Process

Before the study begins, the infusion monitoring system software will be developed and made operational. In the pilot phase, a preliminary observation will be carried out in the designated clinics to determine the baseline incidence of complications.
In the implementation phase, the use of the infusion monitoring system by nurses and its effectiveness will be evaluated.

Pilot Implementation of the Study

During the pilot implementation, complications related to peripheral venous catheters will be monitored in both the experimental and control clinics for a period of two months, aiming to observe a total of 102 catheters.
Subsequently, nurses in both intensive care clinics will receive training on correct catheter placement, prevention strategies, and maintenance.
The usability of the infusion monitoring system will be tested by installing the application on mobile devices (smartphones/tablets) used by two nurses in the experimental group. The nurses will use the application for one day during patient care, and their feedback regarding the usability and technical performance of the system will be collected for necessary improvements.

Study Implementation Phase

Each nurse will use the application on their own smartphone/tablet or another technological device. Nurses will use the electronic infusion monitoring system during patient care for one month. Afterward, the incidence rates of peripheral venous catheter complications will be re-evaluated in both the control and experimental clinics using the same two-month monitoring protocol with 102 catheter observations.
It is expected that the use of the infusion monitoring system will allow nurses to monitor infusion initiation, termination, and intervals more efficiently, enabling faster decision-making and optimized interventions for preventing and managing complications.
As a result, it is anticipated that patient safety will increase, and the quality of care processes will improve. The control group will continue routine care procedures without the use of the system.

Data Analysis

The collected data will be transferred into the computer using the Statistical Package for Social Sciences (SPSS) version 23.0.
Sociodemographic characteristics will be analyzed using frequency and percentage distributions. Data from the data collection forms will be analyzed using Pearson/Spearman correlation tests.
Normality of the data will be assessed with the One-Sample Kolmogorov–Smirnov test. Within-group comparisons will be conducted using ANOVA/Friedman tests, and between-group comparisons across days will be analyzed with ANOVA/Kruskal-Wallis tests. All data will be evaluated at a significance level of $p<0.05$ with a 95% confidence interval.

Ethical Considerations

Before starting the study, ethical approval was obtained from the Scientific Research Ethics Committee of Karadeniz Technical University, Faculty of Health Sciences (Ethics Committee Approval No: 2025/34 – Date: 09.05.2025).
All patients and their relatives included in the study were informed about the purpose and plan of the research and provided both written and verbal informed consent.
At all stages of the study, the principles of the Declaration of Helsinki were strictly followed.