## Abstract

# Infusion Safety in Oncology: Protocol for a Multicenter Study of Air-in-Line Alarms During Antineoplastic Drug Administration

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**Introduction.** Intravenous antineoplastic therapy is a highly complex process in which apparently technical issues may affect treatment continuity, healthcare professionals' workload, and the overall safety of the care pathway. Air-in-line alarms represent a significant concern, particularly during the administration of foaming drugs because of their greater tendency to generate microbubbles within infusion lines. Despite the clinical and nursing relevance of this phenomenon, evidence concerning alarm frequency and independent comparisons of different infusion technologies remains limited.

This study aims to investigate the factors associated with the occurrence and management of air-in-line alarms during antineoplastic drug administration.

**Methods.** A multicenter, observational, prospective, multiphase, and multimethod study protocol was developed involving five Italian centers. The study comprises three complementary phases: a preclinical simulation phase using a manikin to compare infusion technologies under controlled conditions; a field-based observational phase using the Entrustable Professional Activities framework to identify the competencies required for the safe management of infusion therapy and related alarms; and a prospective multicenter observational phase assessing alarm frequency and type, management time, operational strategies, and healthcare professionals' user experience. The study was approved by the National Ethics Committee of the Italian National Institute of Health and was registered on ClinicalTrials.gov as AIR-ONC (NCT07718711).

**Results.** As this is a study protocol, no empirical results are currently available. The planned analyses will integrate simulation, observational, and real-world data to identify the technological, clinical, and organizational factors associated with air-in-line alarms, compare different infusion technologies, and describe the operational impact of these alarms on clinical practice.

**Discussion.** This protocol addresses a relevant problem in everyday oncology practice through an approach integrating infusion technology, nursing competencies, and usability considerations. The findings may support the development of evidence-based recommendations, targeted educational interventions, and organizational strategies aimed at improving patient safety, treatment continuity, and the quality of oncology nursing care.

**Keywords**: Oncology Nursing, Infusion Safety, Antineoplastic Drugs, Air-in-Line Alarms, Infusion Technology, Patient Safety



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