Cover Page

Official Title: Effect of Fan Therapy on Dyspnea Associated With Ticagrelor Administration in Intensive Care Patients

NCT Number: Not yet assigned

Document Date: 18 July 2024

Prepared by: Emine Tuğba Yorulmaz, PhD Student

Supervised by: Asst. Prof. Arzu Erkoç

Document Type: Study Protocol

Study Protocol

1. Study Objectives

Primary Objective: To determine the effect of fan therapy on ticagrelor-associated dyspnea in intensive care patients.

Secondary Objectives: To assess the incidence, severity, and number of dyspnea episodes following ticagrelor administration with or without fan therapy.

2. Study Design

Interventional, randomized, parallel assignment.

Two arms: Control (Standard Care) and Experimental (Standard Care + Fan Therapy).

Masking: Single (Outcomes Assessor).

Enrollment: 110 participants (55 per group).

Study Duration: Approximately 2 days per patient.

3. Interventions

Arm	Intervention	Description
Experimental	Standard Care + Fan Therapy	Standard care plus hand fanning for 5 minutes at 30, 60, 120 minutes after ticagrelor administration. Fan directed toward patient's face from ~15 cm. Dyspnea severity and number of episodes recorded. Device: Hand Fan.
Control	Standard Care	Routine ward care including semi-Fowler position and breathing exercises. Presence, number, and severity of dyspnea attacks recorded during first 2 hours after ticagrelor administration.

4. Outcome Measures

Incidence of Dyspnea

Description: Number of patients experiencing dyspnea within 2 hours after ticagrelor administration.

Time Frame: T1=Baseline, T2=30 min, T3=60 min, T4=120 min

Unit of Measure: Number of patients

Severity of Dyspnea

Description: Dyspnea severity measured using the Modified Borg Dyspnea Scale (0–10).

Time Frame: Same as above

Unit of Measure: Score (0–10)

Number of Dyspnea Episodes

Description: Total number of dyspnea episodes per patient during the first 2 hours.

Time Frame: Same as above

Unit of Measure: Count

5. Randomization

Participants randomized using randomizer.org; Set 1=Control, Set 2=Experimental.

6. Statistical Analysis Plan

Sample size calculated for 2 conjugate groups ($\alpha=0.05$, $\beta=0.20$, power=0.80, effect size=0.10).

Minimum n=100, adjusted to 110 to account for data loss.

Analysis performed by a statistician not involved in data collection.