Study Design of the NUTRI-GUARD Trial - A Phase 3 Adaptive-Design Trial Comparing Catheter Locking Solutions of Taurolidine and Heparin vs. Heparin Only on Central Line-Associated Bloodstream Infections in Adults Receiving Parenteral Nutrition via a Central Venous Catheter

Joseph Kindler, Jared Crandon, Mary Joan Benedict, Liz Hurlburt
CorMedix Therapeutics, Berkeley Heights, New Jersey, USA

Corresponding author:
Joseph Kindler
jkindler@cormedix.com

1. Background

- Central line associated bloodstream infections (CLABSI) are a common complication in patients with intestinal failure requiring parenteral nutrition (PN) via a central venous catheter (CVC).[1,2]
- Along with essential practices, CLABSI prevention guidelines from the Centers for Disease Control and Prevention (CDC) and the Society for Healthcare Epidemiology of America (SHEA) encourage use of antimicrobial catheter lock solutions (CLS) for select patients.[2,3]
- Taurolidine is a non-antibiotic antimicrobial that has a broad spectrum of activity and no known resistance (**Fig. 1**).[4,5] It is approved for use outside of the US as a CLS for the prevention of CLABSIs in PN patients. A meta-analysis of studies in PN patients concluded that taurolidine CLS showed superior efficacy in catheter-related bloodstream infection (CRBSI) prevention over heparin only CLS.[1]
- The LOCK IT-100 trial reported a 71% reduction in the incidence of CRBSIs in adults with end-stage kidney disease requiring chronic hemodialysis via a CVC following use of a CLS that contained taurolidine and heparin vs. heparin only.[6] Adverse reactions were similar across both groups. In November 2023, the US FDA approved taurolidine (13.5 mg/mL) and heparin (1,000 U/mL) CLS for the reduction in the incidence of CRBSI in the limited and specific population of adult kidney failure patients requiring chronic hemodialysis through a CVC.[7]
- The NUTRI-GUARD trial is a Phase 3, randomized study to demonstrate the efficacy and safety of taurolidine/heparin CLS in adult participants receiving home PN via CVC compared to heparin CLS (**Fig. 2**).

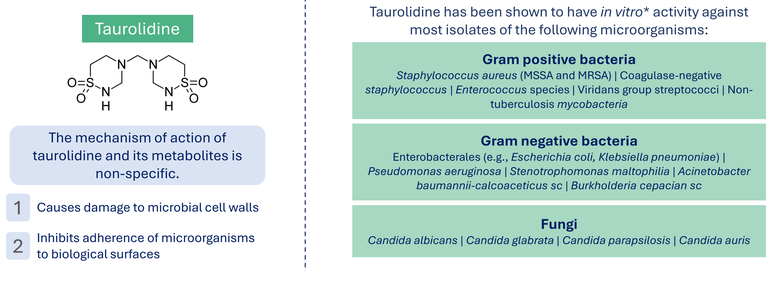

Fig 1. General overview of the mechanism of action of taurolidine (left) and in vitro activity of taurolidine against common microorganisms (right).[4,5] *Clinical relevance is unknown.

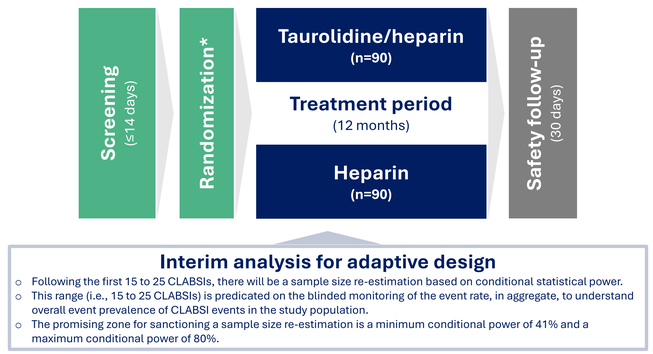

Fig. 2. NUTRI-GUARD study overview. *Randomization will take place prior to the first PN treatment.

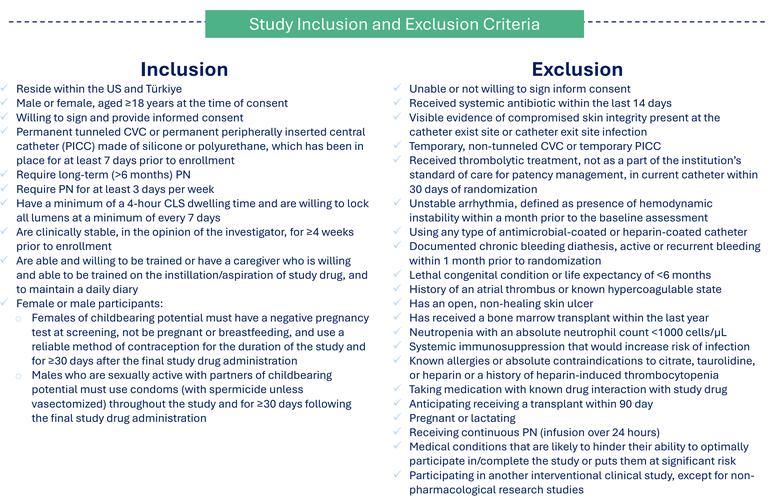

Fig. 3. Full inclusion and exclusion criteria for the NUTRI-GUARD trial.

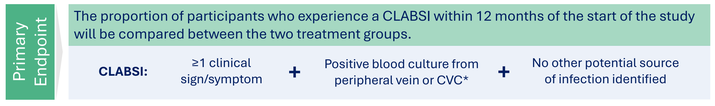

Fig. 4. Description of primary endpoint for the NUTRI-GUARD trial. *If a commensal pathogen is isolated, a secondary confirmatory blood culture is required.

2. Study Design

- NUTRI-GUARD (NCT06822426) is an ongoing Phase 3, randomized, double-blind, controlled, adaptive, 2-arm, multicenter study conducted in the USA and Turkey.
- Study inclusion and exclusion criteria are presented in **Fig. 3**.
- Following screening to ensure eligibility, patients were randomized 1:1 to CLS containing either taurolidine (13.5 mg/mL) and heparin (1,000 U/mL; DefenCath®)[7] or heparin (1,000 U/mL) only.
- The intervention involved the patient or caregiver instilling the CLS into the lumen(s) of the CVC at the end of each PN session or catheter use. The CLS will dwell in the CVC until accessed again, at which point it will be aspirated and discarded.
- The primary endpoint is the proportion of patients who experience a CLABSI and secondary endpoints include adverse events (**Fig. 4**). Clinical evaluations, vital signs, and physical exam findings will also be assessed.
- Following the 12-month intervention, the 30-day safety follow-up period will commence, and participants will switch to standard of care CLS.
- The desired sample size is n=90/group, providing 80% statistical power. Following the first 15-20 CLABSI events, an Independent Data Monitoring Committee will perform an interim analysis and will increase the target sample size if the number of events is below the planning estimates.

3. References

[1]Vernon-Roberts et al. J Parenter Enteral Nutr. 2022;46:1535-1552. [2]Buetti et al. Infect Control Hosp Epidemiol. 2022;43(5):553-569. [3]O'Grady et al. Clin Infect Dis. 2011;52(9):e162-e193. [4]Shah et al. Antimicrob Agents Chemother. 2002;46(6):1674-9. [5]Simon et al. BMC Infect Dis. 2008;8:102. [6]Agarwal et al. Clin J Am Soc Nephrol. 2023;18(11):1446-1455. [7]DefenCath (taurolidine and heparin) [package insert]. CorMedix Inc. 2023.

4. Disclosures

JK, JC, MJB, and LH are employed by CorMedix Inc.

All trademarks are the property of their respective owner(s).
© 2026 CorMedix Inc. All rights reserved.