Reduction of Calciphylaxis-Related Infections with Hexasodium Fytate Treatment in A Randomized, Double-Blind, Phase 3, Placebo-Controlled Trial

ISN INTERNATIONAL SOCIETY OF NEPHROLOGY

CALCIPHYX

COHORT

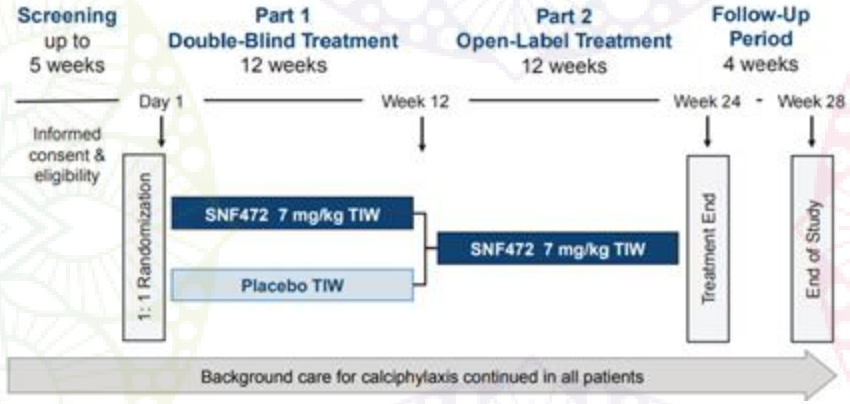
International Multicenter

71 dialysis patients with ulcerated calciphylaxis lesion and pain visual analogue scale (VAS) score ≥50/100

Randomised 1:1, double blind, placebo-controlled trial

METHODS

Study drug (hexasodium fytate {SNF472} 7 mg/kg or matching placebo) was administered intravenously over 2.5–3 h during haemodialysis sessions

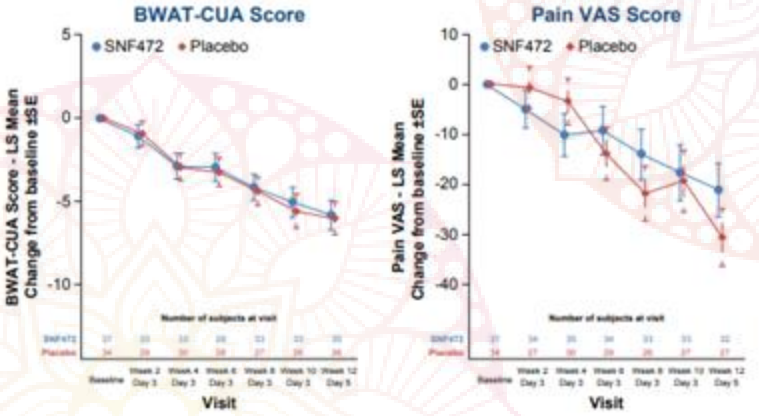


Primary outcome:

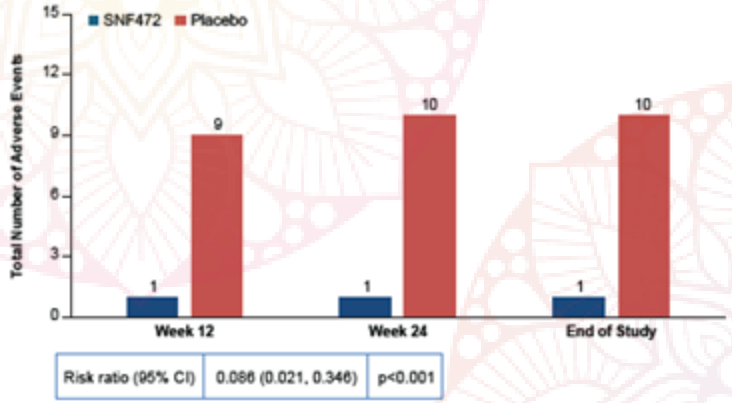
1. Bates-Jensen Wound Assessment Tool (BWAT-CUA)
2. Patients self-reported wound-related pain using a visual analogue scale (VAS)

RESULTS

Primary outcomes



Post-hoc: Calciphylaxis-related Infection



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Conclusion: In CALCIPHYX, both groups showed similar improvements, but more patients on SNF472 completed the study. The placebo group had more deaths and calciphylaxis-related infection.

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