

KiteLock 4% EDTA Lock Solution for the Prevention of Occlusions in Children With Intestinal Failure

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 4 weeks to 18 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Patients managed by the intestinal rehabilitation program at one of the participating centers.
2. Diagnosis of intestinal failure defined as need for PN support for >60 days in previous 74 days for primary intestinal disease (short bowel syndrome, primary motility disorder, mucosal enteropathy).
3. Expectation of the treating physician that the patient will require PN for at least 6 months following enrollment.
4. Age less than 18 years at diagnosis but greater than 4 weeks chronological age or 40 weeks estimated gestational age, whichever is greater.
5. Stable TPN cycling (4 hours off TPN minimum per day) enabling home TPN management
6. Presence of a tunneled central venous catheter (CVC), port-a-catheter, or peripherally inserted central catheter (PICC).
7. Clinical stability for at least 4 weeks and no acute medical comorbidities.
8. A minimum dwell time of 4 consecutive hours daily.
9. Care provider willing to provide informed consent to participate in the trial and willing to comply with randomization and study protocol.

Exclusion Criteria:

1. A temporary CVC (jugular or femoral) or peripheral catheter.
2. Patients receiving long-term PN, but not due to a primary intestinal disorder (i.e., oncology patients or premature neonates on PN due to intestinal immaturity).
3. Known hypersensitivity, allergy, or reaction to EDTA.
4. Pregnancy or nursing mother.
5. Participation in another investigational device or drug trial within 30 days prior to enrollment (unless approved by the principal investigators of the trial).
6. Severe coagulopathy (platelets <50,000, or INR > 1.5).
7. Diagnosis of immunodeficiency disorder.
8. Unstable medical condition requiring hospital admission
9. Received antibiotic therapy for CLABSI within last 14 days.

Conditions & Interventions

Interventions:

DEVICE: KiteLock 4% Sterile Catheter Lock Solution, DEVICE: Heparin Lock Solution

Conditions:

Pediatric Intestinal Failure

Keywords:

catheter lock solution, pediatric intestinal failure, intestinal failure, central venous catheter, KiteLock 4%, heparin, total parenteral nutrition, parenteral nutrition

More Information

Description:

A multi-site, randomized, 2-arm open-label trial to determine if 4% Tetrasodium (EDTA) catheter lock solution is more effective than heparin lock (standard of care) in preventing central venous catheter occlusions in children with intestinal failure (IF) on total parenteral nutrition (TPN).

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Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT05879835

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