

# Safety Study of SMOFlipid to Evaluate the Risk of Developing EFAD and/or PNAC in Pediatric and Adult Patients

NCT06049680

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Status	RECRUITING
Phase	Phase 4
Sponsor	Fresenius Kabi
Enrollment	100 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Age Limits: and Adults
- Male or female patients, at least 1 month of age.
- Patients who require PN for at least 5 days/week.
- Patients who receive 80% or more of their total energy requirements as PN at enrollment and who are expected to receive 80% or more of their total energy requirements as PN for at least 56 days.
- Written informed consent. In case of pediatric patients, informed consent must be obtained from parent(s) or legal representatives. If possible, the assent of the pediatric patient must also be obtained (according to local law).

### Exclusion (17)

- Use of any other lipid injectable emulsion than SMOFlipid within 6 months prior to study participation
- Known hypersensitivity to fish, egg, soybean, or peanut proteins, or to any of the active ingredients or excipients of SMOFlipid.
- Hyperlipidemia or disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentration  $\geq 250$  mg/dL in infants or  $\geq 400$  mg/dL in older pediatric and adult patients).
- Inborn errors of amino acid metabolism.
- Cardiopulmonary instability (including pulmonary edema, cardiac insufficiency, myocardial infarction, acidosis and hemodynamic instability requiring significant vasopressor support).

... and 12 more (see full listing online)

## Locations (5 total)

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Emory University Hospital, Atlanta, Georgia, United States  
The University of Chicago, Chicago, Illinois, United States  
Riley Hospital for Children, Indianapolis, Indiana, United States  
... and 2 more locations

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<https://clinicaltrials.gov/study/NCT06049680>

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