Pharmacokinetics and Safety of Commonly Used Drugs in Lactating Women and Breastfed Infants

NCT03511118

Status	RECRUITING
Sponsor	Duke University
Enrollment	1,600 participants

Key Eligibility Criteria

Inclusion (2)

- Lactating women who are receiving at least one DOI per SOC who are d180 days postpartum, and their infants (d180 days of age) who receive maternal breastmilk.
- Informed consent/HIPAA obtained, according to local IRB/REB/IEC guidelines, prior to any study-related procedures. Lactating women who are not legal adults and their breastfed infants may be enrolled if they assent to participate in the study and consent is obtained from their legal guardian according to local IRB/REB/IEC guidelines.

Exclusion (2)

- Any concomitant condition which, in the opinion of the physicians providing patient care or the principal investigator conducting the study, would preclude a subject's participation in the study.
- Known pregnancy during PK sampling.

Locations (22 total)

University of California-San Diego Medical Center, La Jolla, California, United States
Loma Linda University Health, Loma Linda, California, United States
Northwestern University, Chicago, Illinois, United States
... and 19 more locations