Maternal and Postnatal Outcomes Study (MOS): A Global Observational Registry Assessing the Safety of Elfabrio® in Women With Fabry Disease and Their Infants During Pregnancy and Breastfeeding

NCT06941025

Status	RECRUITING
Sponsor	Chiesi Farmaceutici S.p.A.
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (3)

- Female patients with Fabry disease who have been exposed to at least 1 dose of pegunigalsidase alfa at any time during pregnancy (defined as having received pegunigalsidase alfa within 30 days prior to the DOC and/or during pregnancy) and/or during lactation, and their infants.
- o DOC, defined as 20/7 gestational weeks, will be calculated from last menstrual period \[LMP\] or ultrasound
- Patient or parent/legally authorized representative must be able to understand and provide consent through an Institutional Review Board / Independent Ethics Committee (IRB/IEC) approved Informed Consent Form.

Exclusion (1)

- None

Locations (5 total)

No physical study sites - Decentralized, web-based registry, Washington D.C., District of Columbia, United States
No physical study sites - Decentralized, web-based registry, Berlin, Germany
No physical study sites - Decentralized, web-based registry, Rome, Italy
... and 2 more locations