

An Open-label Study to Investigate ECUR-506 in Male Babies Less Than 9 Months of Age With Neonatal Onset OTC Deficiency

NCT06255782

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| Status | RECRUITING |
| Phase | Phase 1, Phase 2 |
| Sponsor | iECURE, Inc. |
| Enrollment | 8 participants |

Key Eligibility Criteria

Inclusion (9)

- Male sex
- Gestational or adjusted (corrected) gestational age \geq 37 weeks
- Age at screening is 24 hours to 7 months
- Weight \geq 3.5 kg and \leq 13.5 kg at screening
- Has received age-appropriate vaccinations

... and 4 more (see full listing online)

Exclusion (11)

- Neonatal diagnosis of severe to profound Hypoxic Ischemic Encephalopathy due to birth injury
- Requiring urgent liver transplant due to liver failure as assessed by the PI.
- Contiguous gene deletion involving the OTC gene and including at least the CYBB gene on the telomeric side or the TSPAN7 gene on the centromeric side.
- Known or suspected major organ injury/dysfunction/anomalies.
- Vital sign abnormalities

... and 6 more (see full listing online)

Locations (10 total)

UCLA Mattel Children's Hospital, Los Angeles, California, United States
Children's Hospital of Colorado, Anschutz Medical Campus, Aurora, Colorado, United States
Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois, United States
... and 7 more locations