Target Trial Emulation for Pharmacologic Treatment of Neonatal Opioid Withdrawal Syndrome

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Not specified
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Infant is ≥ 36 weeks' gestational age
2. Infant had antenatal opioid exposure identified by at least one of the following:
    1. History of maternal opioid use during the second and/or third trimester of pregnancy as noted in the mother's or infant's medical record;
    2. Positive maternal toxicology screen for opioids during the second or third trimester of pregnancy; and/or
    3. Positive infant toxicology screen for opioids during the initial hospital stay.
3. The infant is being assessed and managed for NOWS at an eligible study site.
4. The infant is at risk for pharmacologic treatment for NOWS defined by either of the following:

- At least 1 score ≥ 8 if assessed and managed with the Finnegan Neonatal Abstinence Scoring Tool (FNAST) or modification thereof
- At least 1 "yes" if assessed and managed with the Eat, Sleep, Console (ESC) care approach
    1. Infant met all inclusion criteria on or after March 25, 2024.

Exclusion Criteria:

1. Infant has major congenital anomalies.
2. Infant has neonatal encephalopathy (inclusive of hypoxic ischemic encephalopathy), a metabolic disorder, stroke, intracranial hemorrhage, or meningitis diagnosed prior to the initiation of pharmacologic treatment.
3. Infant is receiving respiratory support (any positive pressure or oxygen therapy) at 48 hours of age.
4. Infant has undergone major surgical intervention prior to or at 48 hours of age.
5. Infant has postnatal opioid exposure prior to the initiation of pharmacologic treatment for NOWS.
6. Infant was outborn and pharmacologic treatment was initiated at the transferring hospital.

Conditions & Interventions

Conditions:
Neonatal Opioid Withdrawal Syndrome
Keywords:
Neonatal Opioid Withdrawal Syndrome, NOWS

More Information

Description:
The goal of this observational study is to learn how two medicines used in routine care-buprenorphine and morphine-affect recovery in newborns (≥36 weeks' gestation) with Neonatal Opioid Withdrawal Syndrome (NOWS). The main questions it aims to answer are: 1. Do infants treated with buprenorphine become medically ready for discharge sooner than those treated with morphine? 2. Does one treatment lead to better overall clinical outcomes than the other? Researchers will compare infants who received buprenorphine with infants who received morphine to see whether one treatment helps babies recover more quickly. Participants will not be asked to do anything. Instead, the study team will collect information already documented in the infant's and mother's medical records securely without any contact or changes to clinical care. No new medicines, procedures, or visits are involved. This study only reviews existing clinical data to better understand which commonly used treatment may support faster recovery for newborns with NOWS.

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