

Pediatric Dose Optimization for Seizures in Emergency Medical Services

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 months to 13 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Witnessed by the paramedic to be actively seizing, regardless of seizure type or duration; AND
- Under the care of a paramedic; AND
- Transported by an EMS agency participating in the study

Exclusion Criteria:

- A prior history of a benzodiazepine allergy; OR
- Known or presumed pregnancy; OR
- Severe growth restriction based on the paramedic's subjective assessment

Conditions & Interventions

Interventions:

DRUG: Standardized seizure protocol, DRUG: Conventional seizure protocol

Conditions:

Seizures

Keywords:

Child, Emergency Medical Services

More Information

Description:

The Pediatric Dose Optimization for Seizures in Emergency Medical Services (PediDOSE) study is designed to improve how paramedics treat seizures in children on ambulances. Seizures are one of the most common reasons why people call an ambulance for a child, and paramedics typically administer midazolam to stop the seizure. One-third of children with active seizures on ambulances arrive at emergency departments still seizing. Prior research suggests that seizures on ambulances continue due to under-dosing and delayed delivery of medication. Under-dosing happens when calculation errors occur, and delayed medication delivery occurs due to the time required for dose calculation and placement of an intravenous line to give the medication. Seizures stop quickly when standardized medication doses are given as a muscular injection or a nasal spray. This research has primarily been done in adults, and evidence is needed to determine if this is effective and safe in children. PediDOSE optimizes how paramedics choose the midazolam dose by eliminating calculations and making the dose age-based. This study involves changing the seizure treatment protocols for ambulance services in 20 different cities, in a staggered and randomly-assigned manner. One aim of PediDOSE is to determine if using age to select one of four standardized doses of midazolam and giving it as a muscular injection or nasal spray is more effective than the current calculation-based method, as measured by the number of children arriving at emergency departments still seizing. The investigators believe that a standardized seizure protocol with age-based doses is more effective than current practice. Another aim of PediDOSE is to determine if a standardized seizure protocol with age-based doses is just as safe as current practice, since either ongoing seizures or receiving too much midazolam can interfere with breathing. The investigators believe that a standardized seizure protocol with age-based doses is just as safe as current practice, since the seizures may stop faster and these doses are safely used in children in other healthcare settings. If this study demonstrates that standardized, age-based midazolam dosing is equally safe and more effective in comparison to current practice, the potential impact of this study is a shift in the treatment of pediatric seizures that can be easily implemented in ambulance services across the United States and in other parts of the world.

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