A PHASE 3/4 RANDOMIZED, DOUBLE-BLIND, DOSE-RANGING STUDY OF THE SAFETY AND EFFICACY OF DEXMEDETOMIDINE (DEX) USED WITH PROPOFOL (PRO) AS NEEDED FOR PROCEDURAL SEDATION OF PEDIATRIC SUBJECTS ???1 MONTH TO <17 YEARS OF AGE UNDERGOING MRI SCANS

Status: Completed

Eligibility Criteria

Sex: All
Age: 1 Month to 16 Years old
This study is NOT accepting healthy volunteers
Key

Inclusion Criteria:

1. Male or female subject â‰¥1 month and <17 years of age. 2. American Society of Anesthesiologists (ASA) Physical Status I, II or III. 3. Requires non-intubated, spontaneous breathing, moderate to deep sedation (NI MDS) for a magnetic resonance imaging (MRI) study with an intensivist, anesthesiologist or other proceduralist in attendance. 4. Duration of the MRI scan is expected to take at least 20 minutes but no more than 3 hours to complete Key

Exclusion Criteria:

1. Pregnant female subjects (including those with an indeterminate or positive pregnancy test); breastfeeding female subjects. 2. Weight on Day 1 before randomization is less than the 10th percentile of weight for age and sex in the US and Japan or is greater than the 95th percentile of weight for age and sex in the US or greater than the 97th percentile of weight for age and sex in Japan based on sponsor-provided growth charts. 3. Planned medical procedure during the MRI scan or post-MRI recovery period. 4. Requires endotracheal intubation or laryngeal mask airway (LMA). 5. Known allergy to eggs, egg products, soybeans or soybean products. 6. SpO2 <93 % on room air -

Conditions & Interventions

Interventions:
Drug: dexmedetomidine, Drug: propofol
Conditions:
MRI Sedation
Keywords:
procedural sedation, dexmedetomidine, propofol, MRI

More Information

Description: This is a randomized, double-blind, dose-ranging study of the efficacy and safety of DEX when used with PRO as needed, for procedural sedation of pediatric subjects â‰¥1 month to <17 years of age undergoing MRI scans in the US and Japan.
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Phase: Phase 4
IRB Number: STUDY00008334
System ID: NCT04237792