

Project Mountain - Comparing SpO2 and SaO2 for Accuracy

NCT06372106

Status RECRUITING
Sponsor Philips Clinical & Medical Affairs Global
Enrollment 560 participants

Key Eligibility Criteria

Inclusion (5)

- Subject aged 18 years or older or parent/legal guardian of subject aged less than 18 years, willing and able to understand and provide written informed consent/assent.
- Weight and/or age within intended use of at least one SpO2 sensor under test at time of enrollment.
- Willing and able to wear study devices in addition to SoC devices and during SoC procedures.
- In-patient within a neonatal or pediatric intensive care unit (e.g. NICU, PICU, PCICU).
- Has arterial access and ability to have arterial blood samples drawn as part of their SoC and analyzed by CO-Oximetry.

Exclusion (9)

- Known pregnancy or lactating females (self-reported)
- Injury, wounds, physical malformation, hyperkeratosis, or compromised/non-intact skin at sensor application site (i.e. fingers, toes, hands, feet, ears, nasal ala). Note: Certain malformations may be allowed if determined it would not affect application of sensor with the pulse oximetry system.
- Self-reported severe contact allergies to standard adhesives or other materials found in pulse oximetry sensors. Note: Subject may be considered eligible if subject can wear non-adhesive sensor.
- Unwillingness or inability to remove nail polish or artificial nails from sensor application site.
- Nail fungus on sensor application site.

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

Locations (5 total)

Phoenix Children's, Phoenix, Arizona, United States
University of Nebraska Medical Center, Omaha, Nebraska, United States
Duke University Medical Center, Durham, North Carolina, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT06372106>

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