Evaluation of Technologies for Neonates in Africa

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03920761	COMPLETED	APRIL 19, 2019	FEBRUARY 17, 2021

STUDY DESCRIPTION

Brief Summary

This is a diagnostic accuracy evaluation and clinical feasibility study of investigational devices (EarlySense and ANNE systems) in a neonatal high dependency unit (nHDU) in a private teaching hospital and a government maternity hospital in Nairobi, Kenya. Neonates who are admitted for routine observation and care will be enrolled.

Condition or Disease: Neonatal Physiology

Intervention/treatment: Device: EarlySense Insight system
Device: Advanced Neonatal Epidermal System

Phase: N/A

DETAILED DESCRIPTION

To further reduce neonatal mortality rate in low resource settings (LRS) in Africa, research is needed to develop and optimize innovations in neonatal care, specifically technologies that are low cost, operator-independent, and highly efficient. The purpose of this study is to produce information and data regarding the performance of two existing multiparameter continuous physiological monitoring devices developed by device developers, EarlySense and Sonica. The clinical trial is intended to provide evidence to establish whether these investigational devices can reliably and accurately measure vital signs in neonates (when compared to verified reference devices) and to assess the feasibility, usability and acceptability of these devices for use in neonates in a LRS in Africa.

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 575 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Evaluation of Technologies for Neonates in Africa

Actual Study Start Date: June 2019

Actual Primary Completion Date: December 2020

Actual Study Completion Date: December 2020

OUTCOME MEASURES

Primary Outcome Measures: 1. Determine the accuracy the investigational devices: Agreement of the relevant measurement [Time Frame: Measurements will be collected at one minute intervals for a minimum of 1 hour]
Agreement of the relevant measurement parameters of interest between the investigational device and the reference device(s) at each observation
2. Determine the clinical feasibility of the investigational devices: Agreement of clinical event detection [Time Frame: Measurements collected at one minute intervals for a minimum of 1 hour]
Agreement of clinical event detection between the investigational device and the reference device(s) at each observation.
3. Assess the feasibility, usability and acceptability of the investigational device: questionnaire [Time Frame: One 30 minute in-depth interview]
Qualitative questionnaire

ELIGIBILITY CRITERIA

Ages Eligible for Study: up to 28 / (18 to 64 years)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
1. Male or female neonate, corrected age of ≤ 28 days.
2. Willingness and ability of neonate's caregiver to provide informed consent and to be available for follow-up for the planned duration of the study.
Exclusion Criteria:
1. Receiving mechanical ventilation or continuous positive airway pressure (CPAP).
2. Skin abnormalities in the nasopharynx and/or oropharynx.
3. Contraindication to application of skin sensors.
4. Known arrhythmia.
5. Presence of a congenital abnormality requiring major surgical intervention.
6. Any medical or psychosocial condition or circumstance that, in the opinion of the investigators, would interfere with the conduct of the study or for which study participation might jeopardize the neonate's health.

CONTACTS AND LOCATIONS

Contacts

Locations

Kenya	Aga Khan University Hospital, Nairobi	Nairobi
Kenya	Pumwani Maternity Hospital	Nairobi

Sponsors and Collaborators

Save the Children

Aga Khan University

University of British Columbia

EarlySense Ltd.

SWICA

Bill and Melinda Gates Foundation

Investigator

Principal Investigator : Mark Ansermino BC Children's Hospital, Canada

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MORE INFORMATION

Other Publications	Ginsburg AS, Nkwopara E, Macharia W, Ochieng R, Waiyego M, Zhou G, Karasik R, Xu S, Ansermino JM. Evaluation of non-invasive continuous physiological monitoring devices for neonates in Nairobi, Kenya: a research protocol. BMJ Open. 2020 Apr 12;10(4):e035184. doi: 10.1136/bmjopen-2019-035184.
Responsible Party :	Save the Children
ClinicalTrials.gov Identifier :	NCT03920761
Other Study ID Numbers :	ETNA
First Posted :	April 19, 2019
Last Update Posted :	February 17, 2021
Last Verified :	February 2021
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	Undecided
Plan Description:	If in the future data sharing is needed, the study will establish appropriate data transfer agreements with other researchers and only de-identified data will be shared.
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	Yes
Product Manufactured in and Exported from the U.S.:	Yes