NIHR | Trauma Management MedTech Co-operative

0014

CASE STUDY

SUREPULSE MEDICAL LTD:

DEVELOPMENT OF A NOVEL NEONATAL PULSE OXIMETER.

surepulse

FOR FURTHER INFORMATION PLEASE CONTACT:

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PROJECT SUMMARY

The NIHR Trauma Management MedTech Co-operative (NIHR Trauma MIC) collaborated with SurePulse Medical Ltd (SurePulse), a UK-based medical device company, on the development of a new device intended to measure blood oxygen levels (oxygen saturation, SpO2) in newborn babies'. These devices are called pulse oximeters. The NIHR Trauma MIC set-up and delivered a clinical investigation in healthy adult volunteers to assess the essential safety and performance of the novel pulse oximeter in accordance with the internationally agreed standard ISO80601-2-61:2017.

CLINICAL NEED

Approximately 10% of babies require breathing assistance at birth. Without quick and efficient care these babies are at risk of poor health outcomes. Pulse oximeters are currently used to monitor SpO2 (a measure of oxygen in the blood) in newborn babies, however these can take a few minutes before readings are available and the values can be inaccurate. The newborn resuscitation guidelines include SpO2 as a critical physiological measure, and SpO2 measurements are important in assessing treatment effectiveness. As a result, there is a need for quick and accurate SpO2 measurement for newborn babies.

THE SOLUTION

SurePulse has developed the SurePulse VSP which is intended to wirelessly and accurately monitor newborn babies' blood oxygen levels. This could allow more parents to hold their babies earlier and more suitable treatment to be provided.

Fig 1. Newborn baby being monitored.

HOW WE SUPPORTED

The NIHR Trauma MIC previously conducted a usability study for a heart rate monitor (SurePulse VS) developed by SurePulse. During this study, paediatric clinical staff highlighted the importance, and unmet need, for SpO2 monitoring in newborn babies. As a result, SurePulse developed the SurePulse VSP, a wireless neonatal pulse oximeter.

The NIHR Trauma MIC involvement and support for the SurePulse VSP has included the below.

- **Identification of a clinical unmet need which supported a successful grant application to Medilink East Midlands.**
- **Development of documentation for a clinical investigation study of 20 healthy adult volunteers (oxygen desaturation study). This was designed to test the SurePulse VSP in line with the internationally agreed standard and incorporated an inclusive recruitment strategy cognisant of skin tone and gender to ensure that the device works for everyone.**
- **Liaising with the TrABC patient and public involvement (PPI) group throughout the design of the study, and facilitation of the group's review of the participant facing documentation.**
- **Completion and submission of an IRAS form, and communication with the REC and HRA, to gather the approvals required for a first-in-human clinical investigation (REC and HRA approval, MHRA Letter of No Objection).**
- **Progression through local R&D approvals to open and run the clinical investigation.**
- **Delivery of an oxygen desaturation study with 19 healthy volunteers within the NIHR/ Wellcome Trust Clinical Research Facility (CRF) with conformity to ISO 80601-2-61:2017. Generation of the evidence required for regulatory approval.**

Fig 2. Clinical investigation study set up in the Wellcome/ NIHR Clinical Research Facility (CRF).

TESTIMONIAL

'SurePulse Medical have had an extremely positive experience working with the NIHR Trauma MIC who supported the set-up and delivery of a clinical investigation for the development of our new device intended to measure blood oxygen levels in newborn babies. Recruitment completed to time thanks to the tremendous effort of the team there. They brought a high degree of experience and professionalism to the project that made our collaboration hugely rewarding and successful. We would certainly work with them again."

Dr James Carpenter, CEO, SurePulse Medical Ltd.