CASE STUDY

CEREBROTECH™ VISOR

REAL-TIME ASSESSMENT OF BRAIN INJURY TO PROVIDE ADDITIONAL INFORMATION AND FACILITATE EARLY INTERVENTION

FOR FURTHER INFORMATION PLEASE CONTACT:

NIHR TRAUMA MIC
www.trumamic.nihr.ac.uk
traumamic@uhb.nhs.uk

CEREBROTECH MEDICAL SYSTEMS
www.cerebrotechmedical.com
info@cerebrotechmedical.com
+1-925-399-5392
PROJECT SUMMARY

The NIHR Trauma Management MedTech Co-operative (NIHR Trauma MIC) has collaborated with Cerebrotech Medical Systems in the evaluation of the Cerebrotech Visor, a non-invasive device consisting of a scanner, console and disposables. The device uses Volumetric Impedance Phase-shift Spectroscopy (VIPS™) technology which provides real-time assessment of the brain's status following strokes and other brain injury, potentially facilitating earlier intervention. Changes in the brain's fluids, such as those involved in stroke, bleeding, or oedema, can be detected by monitoring fluctuations in intracranial electrical properties, called bioimpedance. These changes are detected by measuring the alterations in low-power (less than that of a mobile phone) radio waves generated by the device as they pass through the head.

HOW WE SUPPORTED

- Provided advice pertaining to the introduction of the Visor into European markets, and associated product beta testing
- Supported applications for grant funding
- Undertook a feasibility study in healthy volunteers to determine how changes in head position alter the device readings
- Orchestrated a usability study to assess how nursing and clinical staff experienced fitting the device onto a simulated patient

Additionally, we facilitated a study, in collaboration with Coventry University, to investigate the usability of the device with 16 paramedics (consisting of lecturers and second year paramedic students) within Coventry University’s Science and Health Building’s ambulance simulator facility. Assistance provided encompassed:

- Usability testing strategy and plan: formative (observational) study
- Evaluation and risk assessment of the user interface (UI)
- Recruitment of representative test participants
- Relevant documentation preparation e.g. consent forms
- Effective moderation of the usability test
- Data management, analysis, and UI recommendations

The results of the usability work have led to valuable feedback, and ongoing improvements being implemented into the device.

The device is CE marked and cleared by the U.S. Food and Drug Administration.

REFERENCES