EMVision Gen 1 Brain Scanner Study on Acute Stroke Participants

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The Australian Stroke Alliance is home to a five-year program of discovery. We are delivering urgent stroke care by road and air across the nation.

In 2021, the Australian Stroke Alliance's Stroke Golden Hour Program received AU$40 million through the Federal Frontier Health and Medical Research initiative. We are laying the foundations for a national and equitable approach to the treatment of urgent, pre-hospital stroke care, particularly for First Nations, rural and remote Australians. Our program brings together over 30 national agencies committed to transforming pre-hospital stroke care. This is a once-in-a-generation opportunity to address an unmet clinical need and to deliver urgent stroke care for all.

BACKGROUND AND AIMS:

Access to imaging devices that can assist in the diagnosis of stroke in the prehospital environment are desperately needed. The Australian Stroke Alliance, in partnership with EMVision are aiming to reduce stroke inequity and bring the hospital to the patient with a lightweight, affordable imaging device. EMVision have developed an imaging device that uses an electromagnetic imaging system operating in the microwave band of the spectrum.

With this study, EMVision aim to acquire datasets from brain scans using the EMVision Gen 1 Brain Scanner + 'ground truth' CT/MRI scans of participants with healthy brains, acute stroke and stroke mimics to advance the AI algorithms of the EMVision Gen 1 Brain Scanner.

FIGURE 1: EMVISION GEN 1 BRAIN SCANNER

METHODS

In stage 1, the device will image 30 healthy participants for baseline healthy brain assessment for hardware qualification and as input for the AI algorithms. Stage 2 will be participants suspected of stroke and include a minimum of 15 haemorrhagic, 15 ischaemic, 10 migraine, 10 seizure and other stroke mimics. A haemorrhagic stroke detection algorithm had been developed based on simulated scan data and augmented real scan data, without fine-tuning with real haemorrhage datasets

All baseline characteristics and endpoints for each study stage will be summarized descriptively. Hardware qualification is quantified as a proportion of successful scans in terms of signal processability.

Scan data will be incorporated into the AI algorithm training dataset to advance the AI algorithms and may be used for preliminary interim analyses to evaluate algorithm performance.

RESULTS

Stage 1 included 30 healthy participants (17 male and 13 female) with a mean age of 63.8 ± 9.29. The hardware had a 100% scan success rate in terms of signal processability.

Stage 2 recruitment remains actively in progress. There have been no adverse events for any patient included in either stage of this study.

A first interim analysis has been completed to indicate the accuracy of the haemorrhagic stroke detection algorithm prior to fine-tuning with real haemorrhage datasets. The preliminary test dataset included 15 patients (5 haemorrhagic, 2 ischaemic, 8 without stroke) that were not included in prior algorithm training. The algorithm correctly identified all 5 haemorrhagic stroke patients (100%), and correctly identified all other patients as without haemorrhage.

CONCLUSIONS

The EMVision Gen 1 brain scanner has further advanced its AI algorithms in the assessment of healthy participants, acute stroke and mimics. Preliminary interim analysis has indicated the accuracy of a haemorrhagic stroke detection algorithm without real haemorrhage scan training data. Continuing recruitment and incorporation of real datasets into the algorithm training dataset remains to be completed, followed by definitive demonstration of the algorithm's capability. While acknowledging that the interim analysis sample size is too small to draw definitive conclusions regarding the algorithm's performance, it serves as an encouraging indicator of the potential for simulation data to accurately represent real-world clinical scenarios.

We acknowledge the Traditional Custodians of Country throughout Australia and recognise their continuing connection to land, waters and sky. We pay our respects to their Elders, past, present and emerging. We are committed to working together to address the health inequities within our Aboriginal and Torres Strait Islander communities. The Uluru Statement from the Heart is a fundamental driver of our research, education program, and commitment to equity and access.

The Australian Stroke Alliance brings together seven principal partners, each committed to transforming prehospital stroke care: