SMARTChip for early diagnosis of suspected stroke

TIMEFRAME: Estimated earliest commercial availability in the UK

Currently unclear
Now
6 months
1 year
18 months
2 years
Over 2 years

TECHNOLOGY

SMARTChip is a point-of-care test to aid in the early diagnosis of stroke. It has been developed by Sarissa Biomedical Ltd.

The test is intended for use in the emergency room and by paramedics on any patient satisfying the FAST (Face, Arms, Speech, Time) algorithm for suspected stroke. The assay uses a hand-held reader and disposable biosensor to measure the level of purines in a finger-prick blood sample. Purines are produced and released by cells undergoing the oxidative stress that occurs during a stroke.

The user initially calibrates a SMARTChip by applying a drop of calibration fluid. The fluid is then removed and a finger-prick drop of blood from the patient is added. The reader is started and the purine level displayed as a numerical value on the device. The process from calibration to final result takes approximately 3-5 minutes. SMARTChip will be used in conjunction with assessment algorithms such as FAST as a rule-in/rule-out test for stroke. The device is expected to assist in triaging patients and routing them to the most appropriate clinical unit.

The company expects to obtain CE marking for a hospital based version of the technology in mid-2017 with a UK NHS launch shortly afterwards. A more portable version suitable for use by paramedics and in ambulances is currently undergoing trials.

POTENTIAL FOR IMPACT

Stroke is the fourth most common cause of death in the UK and is also the major cause of adult disability. Thrombolytic medications which remove blood clots are highly effective at minimising the impact of stroke if used early after the acute event; every 15 minute delay in
treatment is estimated to add, on average, an additional month of disability for the patient. A confirmed diagnosis of ischaemic stroke is required before treatment is started and ischaemic stroke is a complex condition to diagnose. Currently, few diagnostic tools exist to help stroke clinicians and first-responders assess the patient and no blood tests are used specifically in the diagnosis of stroke.

During a stroke, cells undergo oxidative stress which leads to the production and release of purines into the blood. Purine levels increase rapidly with blood levels correlating with the severity of the stroke and volume of brain tissue damaged. Given the extremely short half-life of purines in blood, purine measurements have not been possible in a clinical setting. SMARTChip, an enzymatic biosensor, solves this problem allowing elevated levels of purines to be detected rapidly in a blood sample.

This point-of-care test will be used in parallel with the existing assessment procedures such as the FAST (Face, Arms, Speech, Time) and ROSIER (Rule Out Stroke In The Emergency Room) algorithms to aid in the triage of patients and allow clinicians to more rapidly diagnose ischaemic stroke. SMARTChip is intended to be used to differentiate between stroke and conditions that mimic the symptoms to ensure appropriate patients are directed into the acute stroke care pathway. The company anticipates that as the clinical evidence for the utility of the test accumulates, it will become a routine part of the diagnostic pathway. The development of a more portable version of the reader that can be carried by paramedics should allow more rapid and accurate triage by first-responders, allowing more selective routing of patients to hyper-acute stroke units or local hospitals. The SMARTChip may also be able to detect purines produced as a consequence of a number of other acute injuries including traumatic brain injury, heart attack and foetal hypoxia.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):
Domain 1 Preventing people from dying prematurely;
Domain 3 Helping people to recover from episodes of ill health or following injury.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


COMPLETED UNPUBLISHED STUDIES


ONGOING STUDIES


The SMARTChip is a hand-held device for use by paramedics and emergency doctors to help identify people who are having a stroke. Symptoms of a stroke such as paralysis and speech problems can be seen in other diseases and doctors need to be sure the patient is having a stroke to give the right treatment. SMARTChip tests for natural products of the body called purines that are released into the blood during a stroke, and can be performed in 3 minutes beside the patient. It will be used with the current tests to improve the speed and accuracy of diagnosis. This will allow patients to be treated more quickly, possibly leading to a quicker recovery.