Cerepress™ and Vittamed 205™ for non-invasive intracranial pressure measurement

**TECHNOLOGY**

Cerepress™, developed by Third Eye Diagnostics, and Vittamed 205™, developed by Vittamed Corporation, are designed to non-invasively measure and monitor intracranial pressure (ICP) via the eye. They are intended to be used in patients with traumatic brain injuries, stroke, hydrocephalus, concussion, neurological conditions and other pathologies that may lead to intracranial hyper- and hypotension.

**Cerepress™**

The Cerepress™ device is based on the principle that ICP is directly related to the pressure within the central retinal vein (CRVP) in the eye. To measure the CRVP, Cerepress™ minimally increases the pressure in the eye until the CRV collapses. The system continuously measures the intraocular pressure whilst the pressure is increased and also records images of the retina. By knowing the intraocular pressure when the vein collapses, the pressure in the vein is indirectly measured. Cerepress™ allows for the simultaneous detection of the CRV collapse and the measurement of intraocular pressure and ICP using algorithms that relate CRVP to ICP. The device gives the user a single point reading of ICP in mmHg.

The company intend the handheld device to be used as a triage tool either in hospital e.g. in patients following removal of invasive ICP monitors or in the community e.g. in an ambulance. It takes approximately one minute to collect the data using the Cerepress™ device and measurements can be performed as many times as needed.

The company expect to receive a CE mark for Cerepress™ in late 2015, and plan to launch the device in the UK following this.
Vittamed 205™

Vittamed 205™ uses Doppler ultrasound to measure blood flow parameters in two parts of the ophthalmic artery (intracranial and extracranial). The device consists of a headframe, an ultrasound transducer, an air cuff and a two depth ultrasonic transorbital Doppler blood flow velocity meter. To measure ICP, the air cuff is inflated to apply gradual pressure to the eye orbit while the ultrasound Doppler scans blood flow parameters in the two sections of the ophthalmic artery. When the blood flow parameters become equal in both sections of the artery, the external pressure applied to the eye orbit is equal to the ICP.

The company claim that the procedure takes approximately 15 minutes and can be performed by a trained operator. The device can be used to measure ICP as needed in both a hospital and outpatient setting, before, during or after intervention or treatment. The Vittamed 205™ system does not require individual calibration.

Vittamed 205™ received a CE mark in July 2014 and the company plan to launch the device in the UK for private and NHS clinical use in late 2015/early 2016.

Other non-invasive ICP monitors measure ICP through the ears. These include the MMS-12 and MMS-14 developed by Marchbanks Measurement Systems, which are currently available to the NHS, and the HeadSense HS-1000 device developed by HeadSense, which is CE marked.

**POTENTIAL FOR IMPACT**

Elevated ICP, or intracranial hypertension, is an unusually high pressure inside the skull, which may happen suddenly (e.g. traumatic head injury, stroke) or build up over time (e.g. brain tumour or infection, hydrocephalus). Elevated ICP can be fatal or cause serious neurological damage if not treated promptly.

Currently, a one off measurement of ICP can be determined by performing a lumbar puncture, where a needle is inserted into the lower part of the spine to measure the pressure in the spinal canal. For more continuous monitoring, ICP bolts can be used. This involves inserting a pressure monitor attached to a ‘bolt’ into the cranium through a hole drilled in the skull. Other invasive devices for continuous ICP monitoring include intraventricular catheters (inserted through the brain into the lateral ventricle) and epidural sensors (placed into the epidural space beneath the skull).

Both companies claim that the key innovative feature of their devices is that ICP can be measured non-invasively without the need for patient-specific calibration. Both technologies are claimed to be portable, easy and quick to use. If proven to be effective, use of such devices may enable earlier diagnosis of elevated ICP, allowing for earlier intervention which may result in improved patient outcomes. In turn, this may lead to a reduction in the length of stay in hospital and intensive care units, and the length of post-discharge rehabilitation, saving NHS costs. Using a non-invasive ICP monitor to accurately triage patients may also reduce the number of unnecessary invasive ICP monitor procedures performed.

The companies that develop these technologies also expect that use of non-invasive ICP monitoring is safer and cheaper than current methods, benefitting both patients and the
NHS. They eliminate the risk of bleeding, infection and other complications associated with current standard of care invasive methods. In addition, they can be used following limited training and in an outpatient setting. It is also suggested that a non-invasive method would address the need for additional long term ICP monitoring data and expand knowledge of how mild or moderate traumatic brain injury relates to ICP.

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

RELEVANT PUBLISHED PAPERS AND ABSTRACTS

Cerepress™


Vittamed 205™


ONGOING STUDIES

Cerepress™

No ongoing studies were identified for Cerepress™.
Vittamed 205™


INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.