CoSense® End Tidal Carbon Monoxide monitor for neonatal haemolytic disease

CoSense® End Tidal Carbon Monoxide (ETCO) monitor developed by Capnia, Inc. is a portable, non-invasive device for the detection of haemolysis in neonates. The CoSense test is for use soon after birth and at additional time points as necessary to monitor the rate of haemolysis.

CoSense® measures ETCO by drawing a sample of gas from the patient’s breath through a CoSense® Precision Sampling Set, one end of which is inserted into one nostril and the other end connects to the CoSense® device. As the breath sample is drawn from the patient the device selects a valid physiologic breath, segments the breath into different parts and collects a gas sample from the end tidal portion of that breath using an algorithm. This sample is transferred to an electrochemical carbon monoxide (CO) sensor, which measures the amount of CO in the sample in parts per million. Acquisition of the sample takes less than a minute, and within another 3 minutes a result is provided on a touch screen to the user.

The ETCO value measured by the CoSense® device can be used for the detection of haemolysis. In particular, it can help risk stratify newborns where the presence of haemolysis with jaundice is a predictor of adverse neurological outcomes such as low IQ, auditory abnormalities and kernicterus. It can also determine which babies are at higher risk and may need better monitoring or quicker treatment.

The CoSense® device received a CE mark in August 2013 and is expected to be launched into NHS clinical use in July 2015.
POTENTIAL FOR IMPACT

Haemolysis is the rupturing of red blood cells (RBCs) and the release of their contents into surrounding fluid (e.g. blood plasma). As the RBCs disintegrate, the haemoglobin is broken into globin, iron and haem. When haem is catabolised, bilirubin and CO are produced. Excess bilirubin production in a newborn can lead to its accumulation in the brain with consequent irreversible damage manifesting as neurological deficits, seizures, abnormal reflexes and eye movements.

Investigation of haemolysis in a neonate includes testing its blood for bilirubin levels, red blood cell count, peripheral smear and antibodies (Coombs test). This might involve repeated blood sampling over a period of time. The company claims that measuring CO levels using the CoSense® device can detect haemolysis with a non-invasive breath test, which is simple to use and minimal training is required. The company also claims a key innovative feature of the CoSense® device is that a valid breath sample can be collected and analysed using an algorithm in circumstances of very high and irregular breath rates in neonates. This is important as neonates cannot follow instructions required in other breath diagnostic devices.

The company claims that newborns with haemolysis can be identified earlier and more accurately using the CoSense® ETCO monitor. They can then be treated with phototherapy at lower levels of bilirubin. Conversely, if there is no haemolysis, newborns can be managed with a higher threshold for treatment, discharged early or receive less rigorous follow-up. It is anticipated that blood tests to detect haemolysis would not be performed in the vast majority of cases, and would be replaced with the CoSense® device.

If proven effective, the CoSense® device should provide a non-invasive method to measure ETCO, which can be used to identify newborns with jaundice who at a higher risk of developing adverse neurodevelopmental outcomes. This may allow doctors to better plan in-patient and post-discharge care.

This technology is predicted to have an impact on the following domain(s) 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**

Measuring end-tidal carbon monoxide of neonates who have severe jaundice, using a rapid, painless, and non-invasive technique. Study 1040173.

**INFORMATION FROM**

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