SmartSensor electronic oral glucose tolerance test for screening for diabetes

TIMEFRAME: Estimated earliest commercial availability in the UK

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

TECHNOLOGY

The SmartSensor oral glucose tolerance test (OGTT) device is an electronic device in development by SmartSensor Telemed Ltd that enables patients to perform an OGTT test from home. It is intended to be used for screening the general population for pre-diabetes and type 2 diabetes, in pregnant women for gestational diabetes, and in gestational diabetes for a return to normal glycaemia at 6 to 12 weeks following birth. It could also be used for screening for cystic fibrosis-related diabetes and new onset diabetes after transplants, and in the vascular screening programme and for monitoring disease progression.

The OGTT measures the body’s ability to metabolise glucose and is used to help diagnose diabetes. During the test, the patient’s blood glucose levels are measured before and two hours after consuming a glucose drink. Patients are required to fast for 8 hours prior to the test, which is usually performed in a clinic. This electronic OGTT kit contains everything needed for patients identified as being at risk of diabetes to perform an OGTT at home.

The wireless device incorporates a timer to allow for timed glucose measurements before and after the glycaemic load is consumed, a temperature sensor to enhance test accuracy, two glucose biosensors for measuring blood glucose levels and a detachable Data Record for capturing test data. Blood samples are obtained from finger pricks and once the test is completed, the detachable Data Record can be mailed for processing. Data is read using a USB NFC reader or a Smartphone using a downloadable app which sends the data for processing, offering alternatives to mailing the Data Record. Test data is processed and results are sent to the appropriate healthcare professional. The device does not require prior training to use and contains intuitive graphical instructions to guide the user through the test.

The company anticipate a CE mark in 2014 with launch for private and NHS clinical use in mid 2014.
POTENTIAL FOR IMPACT

The company claim that a key innovative feature of this device is that it integrates the test results into electronic records, allowing the OGTT to be performed successfully from home by untrained patients with results only available through a doctor or nurse. They also highlight that the device’s user-friendly design makes the device accessible to all. The OGTT is considered the gold standard for diagnosing diabetes, and the company claim that the device offers an effective test for screening that will identify more prediabetes and type 2 diabetes than alternative available tests.

As this test can be performed at home and may be more convenient for patients and clinicians, the company expect that the device will improve access to OGTTs, allowing for earlier and more widespread screening for prediabetes and type 2 diabetes. An earlier diagnosis would allow for earlier treatment and, for those diagnosed with prediabetes, early intervention may prevent the onset of type 2 diabetes. In the case of gestational diabetes (GDM), an OGTT at an earlier point in pregnancy could potentially improve outcomes for both the mother and baby.

The company also anticipate that the device would allow for more widespread post-partum monitoring of GDM as the company claim that currently, a substantial proportion of mothers do not get the recommended tests following birth. In addition, screening for cystic fibrosis related diabetes in a home setting would be beneficial to people with cystic fibrosis, and the company also think that inclusion of an OGTT in the vascular risk assessment programme would add significant value to the screening programme.

The company expect that use of the electronic OGTT device would remove the key logistical and resource barriers to delivering OGTTs e.g. the need for trained clinic-based staff and laboratory access. Furthermore, they anticipate that use of the device will result in significant cost savings through a reduction in the use of NHS facilities for performing OGTTs and will enable service re-organisation.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


COMPANY INFORMATION

The company are currently at an advanced stage of discussions regarding clinical trials in the UK for screening for GDM, cystic fibrosis related diabetes and monitoring for GDM mothers post birth. They plan to initiate these trials in 2014.

They are also discussing studies for screening for prediabetes and type 2 diabetes in the UK. In addition, performance evaluation and optimisation work is being undertaken at Swansea University as part of ongoing product development.

INFORMATION FROM

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