

MULTI CENTRE OPEN-LABEL CLINICAL STUDY OF THE SUGARBEAT® NON-INVASIVE CONTINUOUS GLUCOSE MONITORING PATCH

Background and Aims:

Continuous Glucose Monitors (CGM) currently available are costly, invasive, and must be worn for prolonged periods of up to 14 days. The sugarBEAT patch developed by Nemaura Medical Inc., is a non-invasive patch that measures glucose levels on the skin at 5 minute intervals. The patch is a daily disposable sensor adhered to the skin that measures glucose drawn out of the skin non-invasively and data viewed on a reader or mobile phone App. A multi-centre open-label clinical study was carried out to determine the safety and performance of the system.



Methods:

Patches were worn on the arm over a period of up to 14 hours and the CGM measured blood glucose every 20 minutes in 23 patients over 65 days in study 1 and every 5 minutes in 6 patients in study 2. The Hemocu was used to measure finger prick glucose values.

Results:

In study 1 the Pearson correlation of 1,502 matched data points was 0.86. The Mean Absolute Relative Difference (MARD) was 18.10%, and 77.7% of the data was in zone A of the Clarke grid. In study 2 a MARD of 15.8 % was achieved with 73 % data in zone A of the Clarke grid. No skin irritation or adverse events were noted.

Conclusions:

This device is planned for launch in 2017, and is expected to provide diabetics with a low cost CGM tool that is user-friendly and avoids the need for inserting a sensor into the skin. This will help improve long term diabetes care and management, and enhance quality of life.

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