gammaCore® for the treatment of medically unexplained symptoms

TECHNOLOGY

The gammaCore® device, developed by electroCore LLC, is a handheld, patient-controlled, non-invasive vagus nerve stimulator (VNS) intended to help adults with medically unexplained symptoms (MUS). The vagus nerve forms part of the autonomic nervous system and runs from the brain via the neck to the chest and abdomen. It innervates many internal organs including the heart, lungs and digestive tract.

gammaCore® can be used by patients with MUS who experience ongoing physical symptoms including headaches, irritable bowel syndrome, gastric motility disorders, anxiety and depression. Patients place the device against the skin on the side of the neck where they can feel their pulse and administer a two minute stimulation to each side of the neck up to three times a day.

gammaCore® has five CE marks for primary headache disorders, bronchoconstriction, epilepsy, gastric motility disorders, and depression and anxiety. These CE marks cover some of the symptoms experienced by people with MUS.

POTENTIAL FOR IMPACT

People with MUS experience multiple symptoms without a known underlying physical cause. Symptoms can include headache, musculoskeletal pain, tiredness, heart palpitations, gastric motility disorders and low-level anxiety and depression. MUS are most common in women, younger people, patients who have recently had an infection or physical illness, those affected by the ill health or death of a relative, and patients who have previously experienced depression or anxiety. People with MUS are estimated to account for up to a fifth of GP consultations in the UK and cost the NHS at least £3 billion each year. During the diagnostic phase, patients may be sent for multiple tests and for specialist investigations and appointments. Doctors can prescribe different drugs specific to each symptom experienced,
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which then increases the risk of drug interactions and adverse effects. Other treatment options include talking therapy, such as cognitive behavioural therapy.

The company state that gammaCore® will be used to treat the underlying neurological imbalance that leads to MUS. The company also state that as a non-invasive VNS treatment option, it will result in fewer adverse effects than the current drug treatment options.

VNS typically involves surgical implantation of an electric stimulator, which is connected to the vagus nerve in the left side of the neck. The company state that gammaCore® is able to provide VNS without the need for any surgical procedures, which may be a cheaper delivery option for VNS therapy. VNS is not generally recommended for people with implanted devices, such as a pacemaker or cochlear implants, or those with coronary artery disease.

This technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):

Domain 2 Enhancing quality of life for people with long-term conditions.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


ONGOING STUDIES


INFORMATION FROM

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

Lay summary

gammaCore® is in development for the treatment of patients with medically unexplained symptoms (MUS). MUS are where patients experience persistent physical symptoms without any known physical cause. gammaCore® is about the size of a mobile phone. Patients place the device on the skin of their neck for two minutes up to three times a day to stimulate the vagus nerve. Stimulation of this nerve is expected to relieve unexplained pain, headaches, gastric mobility disorders and other symptoms. The company which make the device say that it may have fewer side effects for patients compared to current drug treatments.