Monarch™ External Trigeminal Nerve Stimulation (eTNS) System for attention deficit hyperactive disorder (ADHD)

TIMEFRAME: Estimated earliest commercial availability in the UK

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

TECHNOLOGY

The Monarch™ external trigeminal nerve stimulation system (eTNS system) has been developed by NeuroSigma. It is a non-invasive nerve stimulation device for the treatment of attention deficit hyperactive disorder (ADHD) in children, young people and adults aged seven years and above.

The Monarch™ eTNS device consists of an external pulse generator and a self-adhesive conductive patch. The patch is applied to the forehead and, when switched on, stimulates the V1 branch of the trigeminal nerve, which carries sensory nerves from the skin of the forehead to the brain. The patch is connected to the external pulse generator which delivers bilateral, high frequency nerve stimulation. Patients can adjust the level of stimulation and will typically use the device at night while sleeping.

The trigeminal nerve is the largest cranial nerve, and provides a pathway for sensory signals to enter specific areas of the brain, such as the brainstem, thalamus and higher cortical centres, which are involved in ADHD.

The Monarch™ eTNS system was CE marked in November 2016 and is available for use in the UK. The Monarch™ eTNS system is also available for use in patients with major depressive disorder and epilepsy.
Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder characterised by a group of behavioural symptoms that include inattentiveness, hyperactivity and impulsiveness. The exact cause of ADHD is unknown but it is believed to be caused by poor transmission of messages in the brain, and in particular by low levels of the neurotransmitters dopamine and norepinephrine, which carry messages from one neuron to another. It is thought that around 2% to 5% of school-aged children may have ADHD and approximately two out of five children with ADHD continue to have difficulties at age 18. ADHD is two to four times more likely to be diagnosed in males than in females, and is associated with poor performance in school and decreased achievement in adulthood.

Although there is no cure for ADHD, symptoms can be managed with educational support, counselling, behavioural therapies and medication e.g. central nervous system stimulants. Medications to treat ADHD should only be used when other interventions have failed and within a comprehensive treatment programme. Central nervous system stimulants have significant side effects such as depression, dizziness, irritability and difficulty sleeping.

The Monarch™ eTNS system is the only non-invasive device approved for ADHD. The company claims that in clinical trials, the eTNS system improved behaviour e.g. inattention, and cognition without adverse effects. The company state that because the device is non-invasive, patients can try the therapy in a low-risk setting and, if they respond, they can continue to use the device. If they do not respond, they can simply discontinue therapy.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework

Domain 2 Enhancing quality of life for people with long-term conditions;
Domain 3 Helping people to recover from episodes of ill health or following injury.

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

The Monarch™ external trigeminal nerve stimulation system (eTNS system) is a non-invasive device to treat attention deficit hyperactive disorder (ADHD) in children, young people and adults aged seven years and above. People with ADHD have behavioural symptoms including inattentiveness, hyperactivity and impulsiveness. Medicines used to treat ADHD have lots of side-effects and are only used in children and adults if other treatments fail.

With the Monarch™ eTNS system, an electrical patch is applied onto the forehead and electrical impulses stimulate nerves in the brain. This can change the way the brain communicates messages. The patch is connected to an external pulse generator and the level of stimulation can be controlled by the patient. The device is used in the home at night whilst sleeping. This is the first non-invasive device approved for ADHD and the developer claims that it may work just as well as medication, but without the associated side effects.