Monarch™ External Trigeminal Nerve Stimulation (eTNS™) System for epilepsy

TECHNOLOGY

The Monarch™ eTNS system has been developed by NeuroSigma. It is a non-invasive nerve stimulation device for the treatment of drug-resistant epilepsy (in patients aged nine years and above), to reduce the number of epileptic seizures. It is intended that this treatment be used in addition to current therapy.

The eTNS device consists of an external pulse generator and a self-adhesive conductive patch applied to the forehead to stimulate branches of the trigeminal nerve, which are located very close to the surface of the skin in the forehead. Patients place the electrical patch on the forehead just above the eyebrows. The patch is then connected to the external pulse generator, which is switched on and patients can adjust the level of stimulation to a comfortable setting. The low-energy stimulus is confined to the soft tissues of the forehead without direct penetration into the brain. Patients will typically use the device in the home, for a period of 12 hours, primarily at night while sleeping.

The eTNS system is designed to provide non-invasive bilateral, high frequency stimulation of the V1 branch of the trigeminal nerve. It has been shown in previous studies that sending sensory input into certain areas of the brain can reduce seizures. The trigeminal nerve is the largest cranial nerve, and provides a pathway for signals to enter specific areas of the brain, such as the brainstem, thalamus and higher cortical centres, which are involved in epileptic seizures.

The Monarch™ eTNS system was CE marked in August 2012 and is available for use in the UK. The Monarch™ eTNS system is also available for use in patients with major depressive disorder (aged nine years and above).

POTENTIAL FOR IMPACT

Around 500,000 people in the UK suffer from epilepsy, which is the result of nerve cells ‘misfiring’ in the brain. The causes include abnormal brain development and an imbalance of the brain’s neurotransmitters. Targeting the trigeminal nerve externally is thought to inhibit epileptic seizures.

Vagal nerve stimulation is currently available as a treatment for epilepsy and involves implanting a pacemaker-like pulse generator and a nerve stimulation electrode to deliver
Intermittent stimulation to the left vagus nerve. This is a hospital-based treatment.

If proven to be clinically effective, the Monarch™ eTNS system may provide a new non-invasive treatment option for epilepsy, available for use in the home. According to the company this treatment could reduce the frequency of epileptic seizures, improve a patient’s mood (depression can be a co-morbidity of epilepsy), improve quality of life and reduce costs for the NHS such as reducing the time spent in hospital. This new device has the potential to be an attractive non-drug treatment option for patients with epilepsy and is not likely to be teratogenic (potentially damaging to an unborn child), which can be a problem in some epileptic drugs. The potential impact on NHS resources and patient care is unclear until more is known on the effectiveness of the Monarch™ eTNS system and its place in the pathway of care for epilepsy.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


[http://www.neurology.org/content/72/10/936.short](http://www.neurology.org/content/72/10/936.short)


[http://www.neurology.org/content/61/3/421.short](http://www.neurology.org/content/61/3/421.short)

**ONGOING STUDIES**

ClinicalTrials.gov. Trigeminal nerve stimulation for drug resistant epilepsy (TNS-STTR).  

**INFORMATION FROM**

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