ATI™ Neurostimulation System for cluster headache

TECHNOLOGY

The ATI™ Neurostimulation System, developed by Autonomic Technologies Inc, is a rechargeable, implantable neuro-stimulator of the sphenopalatine ganglion, designed to relieve the acute pain of cluster headache and to reduce the frequency of cluster headache attacks.

The sphenopalatine ganglion is a nerve bundle located in the mid-face behind the root of the nose that is associated with the pain of cluster headaches. It is thought that stimulating the sphenopalatine ganglion reduces the pain experienced during a cluster headache for some patients.

The ATI™ Neurostimulation System comprises an implantable on-demand neurostimulator, programmer software and a rechargeable remote controller. The neurostimulator is implanted through a small incision in the gum above the second molar, on the side where the pain is predominate. During a cluster headache attack, the patient can activate the stimulator by placing the remote control on the cheek. When stimulation is activated the patient feels a mild tingling sensation. When the remote control is removed from the cheek, the stimulation stops immediately.

The company states that unlike other implantable neurostimulators (such as deep brain or occipital nerve stimulation) the ATI™ Neurostimulation System is less invasive (the procedure is similar to minor oral surgery) and leaves no external scarring. The system is also MRI compatible and its design eliminates lead migration and the need to surgically replace the implanted neurostimulator due to battery depletion as the system is inductively powered by a rechargeable remote controller.

The ATI™ Neurostimulation System is CE marked and the company is planning to commercialise the product in the UK.
Other technologies for this patient group include: the Leiden University Medical Center is studying occipital nerve neurostimulation system for the treatment of intractable chronic cluster headache [http://clinicaltrials.gov/show/NCT01151631](http://clinicaltrials.gov/show/NCT01151631).

**POTENTIAL FOR IMPACT**

Cluster headaches are attacks of severe pain in one side of the head, often behind the eye. Cluster headaches are generally very severe and can have a significant effect on quality of life. They are generally more painful than the more common types of migraine or any other type of headache. They are called cluster headaches because those affected usually get one or more of these attacks every day for several weeks or months, before they subside. Cluster headaches are rare and affect around 1 in 1,000 people. Anyone can be affected, but approximately 8 out of 10 people who have them are men.

Treatment for cluster headaches includes an injection with sumatriptan, a nasal spray containing zolmitriptan, or breathing 100% oxygen. The National Institute for Health and Care Excellence recommends that verapamil is considered as a preventative treatment for cluster headaches. Methysergide tablets are also effective at preventing cluster headaches and can be used when other treatments are not effective. An occipital nerve block, an injection of a local anaesthetic, such as lidocaine, into the back of the head can relieve the pain of cluster headaches for a period of time. Deep brain stimulation is a further treatment option, but it is not routinely used in the NHS. For some patients, these treatments are not effective, other patients may become resistant to these therapies.

If proven to be clinically effective, the ATI™ Neurostimulation System may provide a new treatment option for people with refractory cluster headaches, for use in the home. This treatment could reduce pain and the frequency of attacks, improve the patient’s quality of life, as well as reduce costs for the NHS. The potential impact on NHS resources and patient care is unclear until more is known on the effectiveness of the ATI™ Neurostimulation System and its place in the pathway of care for cluster headache.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


Abstracts – provided by the company


COMPLETE UNPUBLISHED STUDIES

No complete, unpublished studies of this device were identified for this alert.

ONGOING STUDIES

ClinicalTrials.gov. Pathway CH-1 long-term follow-up.

ClinicalTrials.gov. Pathway CH registry

**INFORMATION FROM**

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