



S T R O K E



Partnering with innovative clinical technology companies to deliver high-quality research
NHS Research Scotland Stroke Network collaborate with Microtransponder Inc to trial the Vivistim® System for treatment of post-stroke upper limb mobility



Headquartered in Texas, USA, MicroTransponder Inc has developed therapies to treat several neurological conditions.

Vivistim® System

The device used in this study is surgically implanted just below the collar bone and delivers electrical stimulation to the vagus nerve. The stimulation, which is given in conjunction with rehabilitation physiotherapy, is believed to cause the brain to be more receptive to the recovery training exercises.

“The results are pretty spectacular. Obviously this study is exploratory, but this raises a lot of hope”
Dr Phillip Gorelick, MD, MPH, American Stroke Association Spokesperson

“Arm mobility is a major problem and is associated with **poor quality of life in patients** who have had a stroke. It is estimated to affect about **75% of all patients in the early months** and remains a permanent issue for about half of patients so new treatments are urgently required.

“The group receiving active stimulation with the device showed a **9-point improvement in upper-limb Fugl-Meyer (UEFM) score**. This magnitude of change would mean different things for different patients, depending on where they start on the scale. If they start at 20 — which is not much function at all — they might regain some grasp ability so they might be able to carry a plate, for example. If they were in the 30s to start with, they would probably already have the grasp function but they would be able to get back to do more specific tasks.”

Prof Jesse Dawson (Lead Investigator)
University of Glasgow; Consultant Stroke Physician, NHS Greater Glasgow & Clyde, NRS Stroke Research Champion

NHS Research Scotland (NRS) efficiently supports clinical research studies from all Life Sciences sector including pharmaceutical, biotechnology and medical technology companies.

We simplify access to Scotland's clinical research infrastructure, including world class facilities, expert investigators and well characterised groups of patients, enabling industry to benefit from:

- **A single point of contact for industry**
- **Single contract draft and commercial price for Scotland**
- **Co-ordinated access to clinical investigators and patients**
- **Strong collaboration between NHS, academia and industry**
- **Streamlined and timely clinical trial approvals**
- **Sustained permissions performance among the best in Europe**
- **Efficient start up and managed delivery**

"Despite this being a complex trial requiring surgical implantation of a medical device, the infrastructure, expertise and support available in Scotland enabled rapid start-up of this study and real-world testing of our device. Our Scottish site was our best recruiter and acted as a trusted partner in the development of our program. We look forward to working with the team on our phase 3 clinical trial."

Frank McEachern, CEO, MicroTransponder Inc.



Vagus Nerve Stimulation: proof-of-concept (Commercial) study

- Approval: January 2013
- First patient: February 2013
- Last patient: April 2014
- Completed: August 2014

Vagus Nerve Stimulation: randomised pilot (Academic) study

- Approval: April 2015
- First patient: June 2015
- Last patient: July 2016
- Completed: November 2017

Vagus Nerve Stimulation: UK-wide, multi-site

- Scotland as UK point of entry
- Led by NRS Stroke Network
- Established procedures for UK-wide working and set-up across 4 nations
- Ongoing study, recruiting 120 patients

"Our NRS Stroke Network brings together Scotland's leading clinicians, academics, carers and patients alongside dedicated commercial support and UK wide engagement. This collaborative environment enables ambitious research projects to be conducted ultimately leading to improved treatment options and better outcomes for patients."

Dr Jesse Dawson, NRS Stroke Research Champion

"This collaboration showcases our national infrastructure in action, demonstrating how NRS can actively enable companies in the development of new technologies aimed at improving treatment options and outcomes for patients."

Dr Steven Burke, Industry Liaison Manager, NHS Research Scotland – Central Management Team (CMT)

To discuss industry partnerships in Scotland contact Dr Steven Burke, Industry Liaison Manager
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The results of this trial were presented at the International Stroke Conference (ISC) 2017 by Lead Investigator Dr Jesse Dawson, and the study was reported in a number of online and print media, including MedScape and WebMD.com. All studies were commercially sponsored.

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