

Supporting High-Quality Clinical Device Interventions: NRS Stroke lead the Vagus Nerve Stimulation trial.

Poster Author: Professor Jesse Dawson, University of Glasgow; Consultant Stroke Physician, NHS Greater Glasgow and Clyde; NRS Stroke Research Champion & Dr Steven Burke, Industry Liaison Manager

NHS Research Scotland (NRS) efficiently supports clinical research studies from all Life Science sectors including pharmaceutical, biotechnology and medical technology companies. Our collaborative research environment enables ambitious research projects to be conducted ultimately leading to improved treatment options and better outcomes for patients.

INTRODUCTION

For patients who have had a stroke, arm weakness is a major problem and is associated with poor quality of life. It is estimated to affect about 75% of all people with stroke and remains a long-term issue in about half of these, so new treatments are urgently required.

The Scottish Government's 2020 Vision makes a commitment to "ensuring that people get back into their home or community environment as soon as appropriate". In this context, NHS Research Scotland (NRS) Stroke Network collaborated with Microtransponder Inc to trial the Vivistim® System, a medical device that stimulates the Vagus nerve. The device aims to improve upper limb function after stroke.

AIMS AND OBJECTIVES

- Strengthen collaborative research environment
- Enable and facilitate ambitious research projects
- Enhance opportunities for clinical trial participation
- Improve treatment options
- Deliver better patient outcomes by helping stroke survivors live more independent lives
- Build links with key industry partners
- Demonstrate Scotland's world-class clinical research infrastructure.

METHODOLOGY

NRS Stroke brought together Scotland's leading clinicians, academics, carers and patients, alongside dedicated commercial support, to facilitate:

Randomised proof-of-concept (Commercial) study, completed in August 2014

Randomised fully blinded pilot (Commercial) study, completed in November 2017

Multi-site trial – based on success of previous trials, ongoing

The Vivistim® device, used in this study, is developed by MicroTransponder Inc, a US-based company developing therapies to treat several neurological conditions.

The device 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.

OUTCOMES AND RESULTS

- Showcased Scotland's ability to deliver high-quality medical device research with Lead Investigator, Professor Dawson, presenting the trials success at leading international conferences and on prominent BBC health show **Trust me I'm a Doctor** (14 Feb 2018)
- Scotland praised by US commercial partner for rapid recruitment and delivery
- Demonstrated Scotland's efficient and responsive research infrastructure and used as exemplar to attract further studies to Scotland
- Participants treated with the device showed promising improvements in the early studies
- Demonstrates Scotland's ability to partner with industry and collaborate on high-quality research into clinical devices and new technologies.

"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 to 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 do more specific tasks."

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

CONCLUSION

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 the device, leading to improved treatment options and better outcomes for stroke patients. This will ultimately lead to survivors of stroke being active in their own home settings for longer, improving quality of life.

"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

REFERENCES

NHS Research Scotland - www.nrs.org.uk
Microtransponder Inc - www.microtransponder.com
Scottish Government, Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision, August 2012
NHS Research Scotland, Vagus Nerve Case Study, September 2017