Magnetically-Enhanced Diffusion System[™] for acute ischaemic stroke

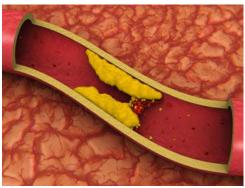




TECHNOLOGY

The Magnetically-Enhanced Diffusion (MED) System[™] in development by <u>Pulse Therapeutics, Inc</u> is designed to improve the delivery of thrombolytic therapy in people who have had an acute ischaemic stroke by using intravenously-injected iron nanoparticles and an externally positioned rotating magnetic field.

The MED system[™] consists of two components: MED Microbeads[™] and the MED Workstation[™]. The MED Microbeads[™] are iron nanoparticles which are intravenously administered immediately after



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thrombolytic therapy such as tissue plasminogen activator (tPA). While the MED Microbeads[™] are being infused, the MED Workstation[™] is placed near the patient's head. When switched on, the internal magnet spins rapidly, which make the MED Microbeads[™] spin and convey towards the clot. This helps to mix the blood containing tPA thus accelerating diffusion and subsequent clot dissolution.

The MED system[™] is intended to be used as a mechanical adjunct to standard of care for patients presenting with acute ischemic stroke and who are eligible for clot-busting drugs.

The MED system[™] is expected to receive a CE mark in Q3 2018 with NHS launch following soon after.

POTENTIAL FOR IMPACT

Ischaemic strokes are the most common type of stroke. They occur when a blood clot forms in an artery leading to the brain, or may also occur within one of the small vessels deep inside the brain thus becoming blocked, and reducing or eliminating the flow of blood and oxygen to the brain. The effects of a stroke vary, ranging from minor limb weakness and speech impairment to permanent paralysis and death. A stroke is a medical emergency and

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the quicker it is diagnosed and treated, the better any recovery will be. If an ischaemic stroke is diagnosed, then a 'clot-busting' thrombolytic drug may be used. Thrombolytic drugs can break down and disperse a clot that is preventing blood from reaching the brain, reducing the risk of death and improving recovery. Treatment needs to be started within 4.5hours of the onset of stroke symptoms.

The company claim that the MED system[™] will accelerate the delivery of thrombolytic medicines to the site of the clot, which may significantly improve patient outcomes. Currently there are no other options in augmenting the delivery of thrombolytic medicines.

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

https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Domain 1 Preventing people from dying prematurely;

Domain 3 Helping people to recover from episodes of ill health or following injury.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS

Derdyn C, Campbel B, Bladin C *et al.* Magnetic particle surface characteristics associated with bradykinin upregulation and hypotension in the CS001 Magnetically-Enhanced Diffusion (MED) of intravenous tPA in acute ischemic stroke feasibility trial. Stroke 2015; 46; supplement 1:020315

Derdyn C, Bladin C, Levi C *et al.* Improved thrombolysis via magnetic enhanced mixing: secondary mechanism for magnetically-enhanced diffusion of intravenous tPA. Stroke 2015;46;supplement 1:020215.

Bladin C, Levi C, Parsons M *et al.* Magnetically-enhanced diffusion (MEDTM) of intravenous tPA in acute ischemic stroke (AIS): a phase 1 feasibility trial. Cerebrovascular Disease 2014; 37; supplement:178-9.

Bladin C, Levi C and Parsons M. Magnetically enhanced diffusion (MED) for improved efficacy of thrombolytic therapy in acute ischemic stroke – a prospective first in man clinical study (NCT01519076). Cerebrovascular Disease 2012;33;supplement 2.

COMPLETED UNPUBLISHED STUDIES

There are currently no completed unpublished studies.

ONGOING STUDIES

The MEDIS – INT study was launched in the UK in February 2017 and is enrolling patients at four sites.

INFORMATION FROM

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

Lay summary

The Magnetically-Enhanced Diffusion (MED) system[™] is a device to speed up the delivery of 'clot-busting' drugs in people who have had an acute ischaemic stroke. Ischaemic stroke happens when a blood clot blocks the oxygen supply to the brain. It is a medical emergency and a 'clot-busting' drug should be administered as early as possible. Iron nanoparticles (Microbeads[™]) are administered intravenously and a magnet is placed over the patients head. As the magnet spins, the Microbeads[™] spin and help the 'clot-busting' drugs to penetrate the stalled blood. The developer says that the MED system[™] is the first device to mechanically accelerate the delivery of thrombolytic medicines to the surface of the clot.