Stay cool, stroke patients to be offered therapeutic hypothermia trial

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(Medical Xpress)—The University of Nottingham is hoping to recruit 20 volunteer patients as part of a European wide study to assess the efficacy of 'therapeutic cooling' in the critical first 24 hours after a stroke. It is thought the treatment could reduce disabilities caused by acute ischaemic stroke – possibly by up to a third.

A total of 1,500 patients are being recruited onto the pan-European trial, EuroHYP-1 with as many as 50 being recruited in the UK. The UK study is being coordinated by Dr Nikola Sprigg, Associate Professor of Stroke Medicine in the School of Medicine and an Honorary Consultant Physician in Stroke Medicine for Nottingham University Hospitals NHS Trust.

She said: "Ischemic stroke happens when a blood clot stops the flow of blood to the brain. Treatments are limited and disability as a result of a stroke is common place. Therapeutic hypothermia – or cooling - reduces the brain's energy requirements, which cuts the demand for blood to the brain and in turn gives our brain cells a better chance of survival. Small hypothermia studies have already been performed in approximately 100 patients in Germany, Denmark and Sweden. Initial results appear to be positive but we can only be sure if we involve hundreds more patients."

Stroke is the second cause of death world-wide and the second biggest cause of disability in high-income countries. In Nottinghamshire alone there are 96,000 stroke survivors many who live with disability as a result.

Dr Sprigg said: "We want as many people as possible to know about this study because we will have to approach patients and their families at what is a very traumatic time for them. We will ask them if they or their loved ones are prepared to take part in the trial, explaining that it may reduce disability after stroke."

As part of the study, participants will be randomly (like tossing a coin) split into two groups, half the people will receive cooling treatment, the other half will have standard care, but no cooling.

Therapeutic cooling has already been effective in cases of cardiac arrest, where it is now routinely used and reduces disability. But in those cases the patient is in a medical coma and doesn't feel the cold. However, stroke patients will be awake as the cooling is performed, using a machine to slowly take their body temperature down to below 35°C. This small but significant drop in temperature will induce some shivering, which can be uncomfortable. Medication will be given to try to prevent shivering and reduce discomfort, and participants will be monitored closely for side effects.

Dr Sprigg said: "It will all happen very quickly after the patient is brought into the stroke unit. We have only an hour and a half after the patient is brought in to ask and receive permission to carry out the therapeutic cooling treatment, because brain cells die very quickly. The first few hours are critical. The treatment must be started within 6 hours of the stroke onset. Treatment lasts 24 hours and there's a 'warming up' period of another 12 hours. Patients will be monitored very closely to look for side effects of the treatment, every 15 minutes for the first few hours and every half an hour after that."

The study starts at the Nottingham University Hospitals NHS Trust City Hospital on 10 March 2014. It will also involve hospitals in London, Newcastle, Liverpool, Leicester, Stoke, Scotland and Ireland. Medical

and nursing staff are being specially trained to carry out the treatment and administer medication to reduce the discomfort caused by shivering. Participants will be given a second brain scan after the treatment as part of the trial to assess the effect of treatment on the brain.

The trial is being carried out in collaboration with Universities across Europe including Edinburgh and Glasgow. It brings together leading experts in statistical design and analysis, therapeutic hypothermia, imaging, health economics, ultrasound, biomarkers and trial execution.

Patient and family advocacy groups have been closely involved, to make sure the design of the study is acceptable to stroke survivors.

Dr Gary Randall, European Research Manager at the Stroke Association, said: "This method of lowering body temperature has long been used to save the lives of patients with cardiac arrest. We are keen to see whether the same process will help reduce the devastating impact of stroke.

"Stroke is currently the largest cause of complex disability in the world, with over a third of stroke survivors in the UK dependent on others. This EU-funded research, supported by the Stroke Association, could play a vital role in providing patients with a better chance of recovery following a stroke."

One in six people will suffer a stroke at some point in their lives. It is nearly as common as cancer. High blood pressure, high cholesterol, smoking, diabetes and an irregular heartbeat can all cause a stroke, many of these are preventable. Stroke is an emergency and people who suspect they are having a stroke, with symptoms such as drooping of the face, difficulties speaking and weakness of the arm should seek medical attention immediately and call 999. Current clot dissolving treatment (thrombolysis) is good but limited the majority of patients will be left with some disability despite getting the best treatment available.

Dr Sprigg said: "So far risks and side effects from this cooling treatment appear to be short lived. It is hoped the trial will help us reduce the long term effects of stroke – but without data from this study we won't know this.

Provided by University of Nottingham