

Final report summary :

**Can mechanical
clot retrieval
improve outcomes
after stroke?**

PISTE: Pragmatic Ischaemic Stroke Thrombectomy Evaluation

PROJECT CODE: TSA 2011/06

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INSTITUTION: UNIVERSITY OF GLASGOW

Why did we fund this research?

Stroke is common, frequently disabling, and has high NHS and societal costs⁽¹⁾. Most strokes are caused by a blood clot blocking an artery in the brain, starving brain tissue of its blood supply and causing tissue to die^(2,3).

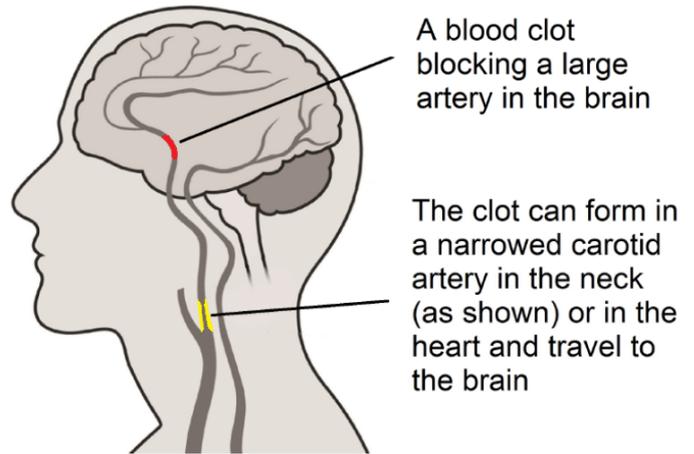
Restoring the blood supply quickly can rescue brain tissue, and 'thrombolysis' treatment with the 'clot-busting' drug rtPA (alteplase) is the current best treatment widely used in the UK. If given within 4.5 hours of stroke onset, it greatly improves the chances of a patient recovering to live independently after their stroke.

However, the success of treatment with rtPA depends on the size of the clot causing the stroke. Blockages of large arteries in the brain are successfully by thrombolysis with rtPA in only 10% or less cases. These large artery blockages cause severe strokes, which are very likely to result in either death or dependence on others. Better treatments for this group of patients are therefore required.

Why was the PISTE trial needed?

The recently-developed technique of intra-arterial thrombectomy (IAT), also called mechanical clot retrieval, offers the possibility of being able to better treat patients with large artery blockages. Under general or local anaesthesia, it can be performed on patients with a clot retrieval device, which is passed through the blood circulation from the groin to the target clot in the brain using a guidewire. The clot is snared and removed. This method can restore blood flow in over 80% of cases. However, the procedure requires specialist facilities, and there was no evidence at the time of the PISTE (Pragmatic Ischaemic Thrombectomy Evaluation) trial starting that clinical outcomes of patients treated this way were improved.

Understanding the appropriate uses of mechanical clot retrieval treatment for acute stroke is of crucial importance. Otherwise any widespread adoption of these expensive treatments risks diverting resources in an unplanned and inefficient way. PISTE is particularly important since it is the only trial of mechanical clot retrieval for stroke in the UK, and therefore representative of NHS practice.



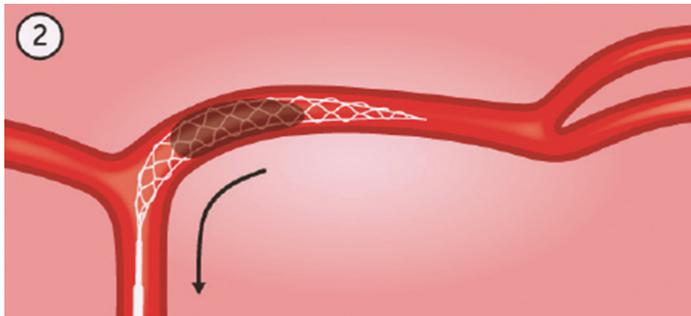
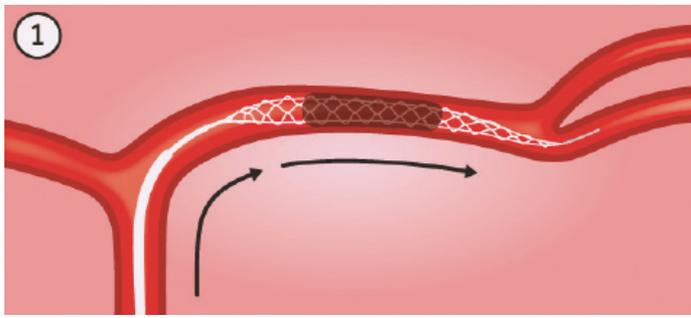
Location of blockage in a large artery in the brain, starving tissue of its blood supply.

What did the researchers do?

The PISTE trial tested the effects of mechanical clot retrieval in acute stroke patients with large artery blockage confirmed on brain scanning. It was a randomised, controlled trial in which all 65 of the participants received current best treatment (thrombolysis treatment with rtPA).

Treatment was started as quickly as possible after stroke onset. Once availability of an expert to perform the mechanical clot retrieval was confirmed, half (33 patients) were randomly allocated by a computer-based system to undergo additional mechanical clot retrieval. The procedure was carried out within strict timelines to ensure rapid restoration of blood flow.

The primary outcome was the effect on recovery at three months after stroke using a standard scale measuring disability: the modified Rankin Scale. Secondary outcomes included early clinical improvement at three months after stroke. PISTE ran successfully in 10 UK hospitals.



Mechanical clot retrieval:

- 1) Capturing clot with stent
- 2) Retrieving stent and clot

The start-up phase of the trial was funded by the Stroke Association. Key trial processes were established, regulatory approvals and adoption on to the National Institute for Health Research Stroke Research Network (NIHR SRN) were obtained and recruitment to the trial was commenced. The start-up phase aimed to recruit approximately 70 patients, and recruited 65 patients.

The NIHR funded the full trial, which aimed to recruit to a target of 400 patients in total. However, between October 2014 and April 2015, results from seven other clinical trials of clot retrieval were reported in other countries, indicating greatly improved chances of recovery in selected patients treated with this technique compared with care alone. Recruitment to PISTE was halted to consider these findings and the trial ceased formally in summer 2015.

What did the research find?

The main findings from the PISTE trial were presented at the International Stroke Conference 2016. At three months after having a stroke, 20% more patients in the group who had received mechanical clot retrieval treatment had made a full neurological recovery, as compared to the group who received standard treatment alone.

As PISTE was stopped early, there were too few patients to reliably assess some other outcomes the trial investigated, although the findings of PISTE are consistent with previously published trials and suggest that treatment with mechanical clot retrieval was effective and safe within an NHS setting, with no significant harmful effects.

The full findings of the PISTE trial await publication in a peer reviewed journal, and are expected to inform UK and international guidelines for care, and be adopted into NHS practice through working parties to develop services.

Data from PISTE will be included in an international collaborative effort to pool data from all of the recent trials in order to answer further questions about the procedure.

References

1. Saka O, McGuire A, Wolfe C. (2009). Cost of stroke in the United Kingdom. *Age and Ageing* (2009) 38 (1): 27-32
2. Intercollegiate Stroke Working Party. National clinical guideline for stroke, 4th edition. London: Royal College of Physicians 2012

What does this mean for stroke survivors?

The PISTE trial suggests that mechanical clot retrieval for the treatment of strokes caused by the blockage of a large artery in the brain can be performed effectively in an NHS setting. It adds to evidence from a number of similar clinical trials showing the effectiveness of the treatment.

The results from the PISTE trial support the more widespread use of mechanical clot retrieval for stroke in the UK, and will inform the planning of how the treatment may be used for maximum benefit to the patient.

We are the Stroke Association

The Stroke Association is the leading stroke charity in the UK. We believe in the power of research to save lives, prevent stroke and ensure that people make the best recovery they can after a stroke.

We're here for you. If you'd like to know more, please get in touch.

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Email: info@stroke.org.uk

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