



# Therapeutic hypothermia for acute ischaemic stroke

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www.nice.org.uk/guidance/ipg647

### Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

#### 1 Recommendations

1.1 Current evidence on the safety of therapeutic hypothermia for acute ischaemic stroke shows that there are serious complications. Evidence on efficacy does not show any meaningful improvement in outcomes.

Therefore, this procedure should not be used. Find out <a href="https://www.why.NICE">why.NICE</a>
recommends not to use some procedures on the NICE interventional procedures guidance page.

## 2 The condition, current treatments and procedure

#### The condition

2.1 Acute ischaemic stroke is characterised by the sudden loss of blood circulation to an area of the brain and a corresponding loss of neurological function. This may lead to symptoms such as numbness or weakness of the face, arm or leg on 1 side of the body, and often problems with speech and swallowing. Stroke severity can be measured using scales such as the National Institutes of Health Stroke scale and the Modified Rankin scale. Broadly, strokes are classified as either haemorrhagic or ischaemic. Acute ischaemic stroke refers to a stroke caused by an arterial thrombosis or embolism. It is more common than haemorrhagic stroke.

#### **Current treatments**

2.2 Patients suspected to be having an acute ischaemic stroke should have

rapid assessment and early intervention with specialist care according to NICE's guideline on stroke and transient ischaemic attack in over 16s.

Recanalisation strategies, such as thrombolysis, attempt to re-establish blood flow so that cells starved of oxygen can be rescued before they are irreversibly damaged. Effective stroke care also includes specialised supportive care and rehabilitation when appropriate.

#### The procedure

- 2.3 The timing, duration and degree of therapeutic hypothermia in trials has varied. Typically, however, cooling has been attempted as close to stroke onset as possible (usually within 6 hours) and continued for at least 12 to 24 hours, with body temperature maintained at 33°C to 36°C. This guidance only refers to the use of therapeutic hypothermia and not to other targeted temperature management approaches that treat or prevent pyrexia.
- 2.4 Before the procedure, the patient's temperature is measured and further temperature monitoring is done continuously with an internal (intravesical, rectal or oesophageal) probe connected to the cooling device. Cooling devices can be surface (ice-cold saline, surface cooling, cooling helmets and nasal cooling) or endovascular systems. After cooling, the body is slowly rewarmed, at a rate of 0.25°C to 0.5°C every hour. Rewarming takes about 8 hours. During cooling, patients need close cardiovascular monitoring in an intensive care environment, and may also need intubation and sedation. Drugs, including neuromuscular blockers, may be used to manage shivering.
- The procedure may be used with thrombolysis (intravenous alteplase), mechanical thrombectomy or other vascular reperfusion techniques.
- The aim of the procedure is to reduce the risk of secondary brain damage.

#### 3 Committee considerations

#### The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 randomised controlled trials (1 of which was a conference abstract and used for safety data only), 3 non-randomised comparative studies and 2 case series. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in mortality and stroke morbidity, and improved quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: worse neurological outcome, pneumonia and bleeding.

#### Committee comments

- There are different methods and different devices used for the procedure.
- There are variations in the degree of temperature control, both in the degree of cooling and the length of treatment period, and target temperatures can be difficult to achieve.
- 3.6 Pneumonia was more common in patients treated with this procedure.
- 3.7 This procedure should be differentiated from targeted temperature management more generally, which also includes treatment and prevention of pyrexia.

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## **Endorsing organisation**

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.