

## **Understanding NICE guidance**

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**Information for people who use NHS services**

# **Controlled cooling to treat newborn babies with brain injury caused by oxygen shortage during birth**

*NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.*

This leaflet is about when and how controlled cooling can be used in the NHS to treat newborn babies with brain injury caused by a shortage of oxygen during birth. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which babies will benefit most from it. This leaflet is written to help parents or carers whose baby has been offered this procedure to decide whether to agree (consent) to it or not. It does not describe brain injury or the procedure in detail – a member of your baby's healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your baby's doctor to help you reach a decision. Some sources of further information and support are on the back page.

## What has NICE said?

This procedure can be offered routinely as a treatment option for carefully selected newborn babies with brain injury caused by oxygen shortage during birth provided that doctors are sure that:

- the parents or carers understand what is involved and agree to the treatment, and
- the results of the procedure are monitored.

It should only be carried out in units that are experienced in the care of very ill newborn babies, by healthcare professionals with special training in cooling treatments.

NICE has encouraged healthcare professionals to enter details of all babies receiving this procedure into a national study.

### Other comments from NICE

There are uncertainties and difficulties in deciding which newborn babies might benefit from this procedure. In particular, there is little evidence about whether to use it for babies with less severe brain injury and there are difficulties in deciding whether some babies are too ill to benefit from it.

## Controlled cooling for newborn babies with brain injury

The medical name for this procedure is 'therapeutic hypothermia with intracorporeal temperature monitoring for hypoxic perinatal brain injury'.

The procedure is not described in detail here – please talk to your baby's specialist for a full description.

A shortage of oxygen around the time of and during birth can cause brain injury in a newborn baby that can lead to death or permanent disability. There are no specific treatments for newborn babies with this type of brain injury, but standard care involves looking after these babies according to their individual needs in a neonatal intensive care unit.

The procedure that NICE has looked at involves lowering the baby's temperature from the normal body temperature of 37°C to a temperature between 33°C and 35°C soon after birth and for a few days afterwards (usually about 3 days). The idea is to cool the brain in the hope of slowing down the processes that cause brain damage. It is usually carried out on babies delivered at 36 weeks or later. In this procedure the baby's body is usually cooled using a special mattress filled with cooled fluid. Sometimes just the head is cooled using a custom-made cap. The temperature inside the baby's body is checked throughout the procedure, usually using a probe placed in the baby's bottom (which measures rectal temperature). After the cooling period, the baby is warmed up gradually until their temperature has returned to normal.

## What does this mean for me and my baby?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your baby's doctor thinks controlled cooling is a suitable treatment option for your baby, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits my baby might get?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will my baby need after the procedure?
- What happens if something goes wrong?
- What may happen if my baby doesn't have the procedure?

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 8 studies on this procedure.

### How well does the procedure work?

One study looked at all the results from 10 separate studies with a total of 1320 babies. Across the 10 studies, the risk of death was lower in the babies who had cooling compared with babies who were treated by standard care. In 3 of the 10 studies (a total of 767 babies) the combined risk of death or severe disability was lower in babies who had cooling compared with those who did not, and babies who were cooled were more likely to have survived without brain damage after 18 months. In the babies who survived, the risks of severe disability or cerebral palsy were higher in infants treated with standard care compared to those who were treated with cooling.

A study of 325 babies reported that 71 out of 163 babies who had cooling and 45 out of 162 babies who had standard care survived without brain damage. Of the babies who survived, fewer of those who were treated with cooling had cerebral palsy (33 out of 120) compared with those who had standard care (48 out of 117).

In a study of 234 babies, 59 out of 108 babies treated with head cooling were reported to have severe disabilities or to have died after 18 months, compared with 73 out of 110 babies treated with standard care.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the success of the procedure can be assessed by survival without brain damage, less severe disability, lower rates of cerebral palsy and better scores in developmental tests.

## Risks and possible problems

In a study of 234 babies, 1 baby had skin problems and bleeding under the cooling cap. There were also 2 separately reported instances of a baby developing skin problems where the cooling materials (ice packs or a cooling mattress) were in contact with the skin.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible complications include problems with metabolism (the chemical processes in the body), problems caused by thickened blood, infections, and fits which can sometimes occur if the baby is warmed up too quickly after treatment.

## More information about brain injury in babies caused by oxygen shortage during birth

NHS Choices ([www.nhs.uk](http://www.nhs.uk)) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may be able to give you further advice and support.

### About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

*To find out more about NICE, its work and how it reaches decisions, see [www.nice.org.uk/aboutguidance](http://www.nice.org.uk/aboutguidance)*

*This leaflet is about 'therapeutic hypothermia with intracorporeal temperature monitoring for hypoxic perinatal brain injury'. This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/guidance/IPG347](http://www.nice.org.uk/guidance/IPG347)*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk) and quote reference N2185).*

*We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.*