

A study of treatment for perinatal asphyxia



TOBY

Parent Information Leaflet

**The results of
the TOBY Study
October 2009**

We are very pleased to be able to tell you that the TOBY Study team has now analysed the results and these have been published in the New England Journal of Medicine, on 1st October 2009. The reference to this publication is:

Moderate Hypothermia to Treat Perinatal Asphyxial Encephalopathy; Azzopardi D, Strohm B, Edwards A, Dyet L, Halliday H, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thoresen M, Whitelaw A, Brocklehurst P; *N Engl J Med*, 2009; 361 (14)

Without the support of you, your family and others like you, we could never have completed this landmark study and we want to share the results of the study with you.

The aim of the TOBY Study was to find out whether cooling babies who have perinatal asphyxia will make a difference to their chances of recovery. In order to find out whether cooling is helpful we compared 'intensive care treatment' with 'intensive care treatment plus cooling'.

How was the Study organised?

Babies who were in the cooled group were cooled so that their temperature was between 33-34 °C for 72 hours (3 days) followed by gradual rewarming.

We collected information about each baby's stay in hospital and at age 18-21 months children were seen by a paediatrician. These assessments mostly took place in hospital outpatient departments, some were held at the child's home, and for a small number of children information was either collected in a telephone interview with the parents, or from medical notes.

Findings

A total of 325 babies took part in this study from 42 hospitals. 162 babies were allocated intensive care and 163 were allocated intensive care with cooling.

- Moderate cooling for 72 hours following perinatal asphyxia did not significantly alter the number of babies who died; this was 44 (27%) babies who were allocated intensive care and 42 (26%) babies who were allocated intensive care with cooling.

- Cooling did not significantly reduce the combined rate of death and severe disability. This occurred for 86 (53%) of the babies who were allocated intensive care and 72 (44%) of the babies who were allocated intensive care with cooling.

However, for children who did survive, cooling did improve some very important outcomes:

- The number of babies who survived without severe disability was significantly higher in the cooled group (28% in the intensive care group versus 44% in the intensive care with cooling group).

- Also, fewer cooled babies had cerebral palsy at age 18 months (41% of babies in the intensive care group versus 28% of babies in the intensive care with cooling group).

- When the results from TOBY are added to those of other studies from elsewhere in the world, it is clear that treatment with cooling increases the number of children surviving without severe disability following perinatal asphyxia.

Treatment allocation and your baby

Now you know the results of TOBY, it is possible that you feel pleased if your child was cooled, or disappointed if not. It must be remembered that there were babies in the cooled group who died or survived with developmental problems, just as in the non-cooled group there were babies who survived with no difficulties.

In a randomised controlled trial such as TOBY this will always happen – individual babies alone do not provide the answer and that is why the greater the number of babies in the study, the more reliable the results are. All the information is combined together in order to show if there is a real difference between the two groups, cooled versus non-cooled; greater numbers make the results more reliable and it is therefore unlikely that the findings have happened by chance.



Publication of the TOBY results

The results of TOBY are published in the New England Journal of Medicine. If you would like a copy of the full paper please return the completed reply slip to the TOBY Co-ordinating Office, or contact us by telephone or email. Our contact details are on the back page.

As a result of this research, neonatologists are in a position to offer care to babies who have perinatal asphyxia that is based on good evidence, evidence that you helped to provide.

A Big Thank You...

The TOBY Study team wishes to express its gratitude to all the families who took part in this study under extremely stressful circumstances shortly after their baby's birth, many of whom continued to support the study in the follow-up phase. Sadly, not all TOBY babies survived to be followed up and our deepest condolences go to their families.

Our sincere thanks must also go to all the neonatal units and staff who took part in the study so enthusiastically, and contributed to its success.

Bliss, the charity that supports sick babies, helped us immensely by hosting the TOBY Parents' Message Board on their website; we know it was a great support to many TOBY families. So, thank you Bliss!



What next?

The Medical Research Council, funders of the TOBY Study, have agreed to fund a further follow-up study so that TOBY children may be seen again at 6-7 years of age, to find out how they have progressed as they grow older. At this age it is possible to collect more detailed information about their abilities and skills that will add significantly to the information collected at 18 months.

Parents whose children were assessed at 18 months were asked if they were happy to be contacted again in the future to be informed about further studies. Almost 100% of those asked agreed to this.

Of course there is no obligation to do so, but naturally we are hoping these families will agree to support us again by allowing their child to take part.

Further research into cooling as a treatment

It is possible that cooling combined with other treatments may give better results than cooling alone. Researchers are already considering what other studies could be performed that could result in further progress in the treatment of babies born with perinatal asphyxia.



The UK TOBY Cooling Register

www.npeu.ox.ac.uk/tobyregister

This Register was established in December 2006, immediately following the end of recruitment of babies to TOBY. In its first 2 years over 300 babies were registered, all of whom had been treated with cooling. Now that the use of cooling as a treatment has been endorsed by the TOBY results, more hospitals are likely to offer this treatment, and provide the Register with information about their experiences.

National Institute of Health and Clinical Excellence (NICE)

www.nice.org.uk/guidance/

During the summer of 2008 a consultation on the use of cooling for the treatment of perinatal asphyxia was held by NICE. They decided not to provide new guidelines however, until they could take account of TOBY's findings. Now that the results of TOBY are being published NICE will be working towards issuing updated guidelines, based on the best evidence available.



The TOBY Study was funded by the Medical Research Council, from 2002 to 2008.

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Help for parents is available:

Bliss (www.bliss.org.uk)

Family Support Freephone Helpline 0500 618140

Monday to Friday 9am - 9pm.

Scope (www.scope.org.uk)

If you would like information on Scope's services, cerebral palsy or any aspect of living with disability, you can call Scope Response, which offers confidential advice and information on 0808 800 3333 9am - 5pm weekdays, closed weekends and Bank Holidays.

You can also email response@scope.org.uk or text SCOPE, plus your message to 80039.



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