ISRCTN 08886155

The TOBY Xenon Study

TOBY Xe

Results Newsletter for Parents
January 2016

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We are very pleased to be able to tell you that we now have the results of the TOBY Xenon Trial and our findings were published on-line in the medical journal Lancet Neurology, on 18 December 2015.

Without the support of your family and others like you, we would not have been able to complete this important study and so we want to share the results with you. It does take a long time to reach the point of publication and we thank you for your patience.

You will remember the aim of the TOBY Xenon Trial was to find out whether adding inhaled xenon gas treatment to cooling treatment would add to the known benefits of cooling for babies who have moderate or severe illness from lack of oxygen at birth (perinatal asphyxia).

How was the Study organised?

Most babies in the study were recruited from three neonatal units, at Queen Charlotte and Chelsea Hospital, University College London Hospital and St Thomas's Hospital. Liverpool Women's Hospital also took part for a limited period.

Ninety-two babies were recruited to the study over two and a half years.

Babies were randomly allocated to receive conventional cooling treatment or cooling treatment plus inhaled xenon gas.

All babies had their body temperature reduced to 33-34°C for 72 hours followed by gradual rewarming. Babies who were in the cooling-plus-xenon group also received xenon gas through their ventilator for 24 hours, from the time that they were randomised to receive that treatment.

We collected information about each baby's stay in hospital, and they had magnetic resonance (MR) studies of their brain before 15 days of age, after rewarming had taken place. The data from the MR studies were used as predictors for future outcomes and whether the baby's development might be affected.

Sadly some babies died and our deepest condolences go to their families.

FINDINGS:

The Study showed that it is safe to treat babies with inhaled xenon gas, and that it can be done sucessfully by experienced staff in an intensive care unit.

The Study also showed quite clearly that adding xenon treatment to cooling did not make any difference to their MR results, ongoing health, or survival, within the duration of the project.

This is valuable information that will help guide clinicians who provide treatment for lack of oxygen at birth to babies, in the future.

For many babies we do know that cooling has some benefits, and clinicians are keen to find additional treatments that might add to those benefits. The information we now have from the TOBY Xenon Study will ensure that clinicians will no longer spend time wondering if adding xenon to cooling might be advisable, but can move on to researching other treatment options.

All the information collected was analysed and there was no difference between the two groups in the end. Despite the small numbers in the study, our methods of analysing the imaging data make it very unlikely that the findings have happened by chance.

Treatment allocation and your baby

Whether or not your baby received xenon in addition to cooling, we must remember that at the time the Study was developed and given funding, nobody knew what the answer would be. Many doctors had been asking the question, as preliminary research indicated it might be beneficial.

Now, with your help, this very important question has been answered.

Both the cooling-only group and the cooling-plus-xenon group of babies are equally important to the study; this will continue to apply to any future follow-up studies with children who took part in the TOBY Xenon Study.

Publication of the TOBY XENON results

The results of the TOBY Xenon Study were published in Lancet Neurology on 18 December 2015:

Moderate hypothermia within 6 hours of birth plus inhaled xenon versus moderate hypothermia alone after birth asphyxia (TOBY-Xe): a proof-of-concept, open-label, randomised controlled trial

Denis Azzopardi, Nicola J Robertson, Alan Bainbridge, Ernest Cady, Geoffrey Charles-Edwards, Aniko Deierl, Gianlorenzo Fagiolo, Nicholas P Franks, James Griffiths, Joseph Hajnal, Edmund Juszczak, Basil Kapetanakis, Louise Linsell, Mervyn Maze, Omar Omar, Brenda Strohm, Nora Tusor, A David Edwards.

You may view a summary on-line at:

http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2815%2900347-6/abstract

If you would like a copy of the full paper please contact the TOBY Xenon Study Co-ordinating Office, FAO Ann Kennedy. The address is on the back page of this leaflet or email *ctu@npeu.ox.ac.uk*

As a result of this research, doctors are in a position to offer care to babies who have had lack of oxygen at birth, which is based on good evidence, evidence that you helped us to provide.

What next?

Although not funded in the original research project, it is possible that clinical follow-up assessments of TOBY Xenon children will take place, to further compare the health of the children from the two treatment groups as they grow older. Unless families have indicated that they would not wish to be contacted again, you will be informed if any future research is taking place.

Of course there is no obligation, but naturally we would hope that families will agree to support us again by allowing their child to take part in any future study, whether their child was treated with cooling alone, or with the addition of xenon.

The TOBY Xenon Study was funded by the Medical Research Council, from 2010 - 2014

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The Chief Investigator was Professor Denis Azzopardi, who was based at Imperial College London.

A BIG THANK YOU…:

The TOBY XENON Study team wish to express their gratitude to all the families who took part in this study under extremely stressful circumstances shortly after their baby's birth. 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.

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