

PARENT'S NEWSLETTER 2010

ICISS – 137 infants have now joined the trial

Hospitals in the Australia, New Zealand, Switzerland and the UK are inviting parents to take part. Germany will soon be joining too.

Dear Parents,

- Again, we first want to say *another* big **thank you** for agreeing to take part in ICISS. We hope that taking part in this trial did not add to your problems at a difficult time.
- This is the third in a series of annual newsletters that we will be producing for ICISS parents.
- We plan to keep you up to date with the progress of ICISS through these newsletters.
- We will try to send you a newsletter every year. This year's letter is a little late as we have been very busy! Last year we wrote to 72 parents who were taking part when the 2009 newsletter went out. Now another 65 parents will see an ICISS newsletter for the first time.
- Copies of all parent's newsletters are placed on the trial website so you can get earlier newsletters if you want to.
- If there are other things you would like to know, do tell us – and we can include popular items next time.

Timescale.

- Many of you will know from last year's newsletter that we have been badly delayed because of all the difficulties in getting approvals to undertake research. We now have to manage further problems with approvals each time a doctor at a centre retires or moves post. This is much more difficult now than it was during our previous study, UKISS, about 10 years ago.
- As a result we remain more than 1 year behind schedule. So it will be longer than we had planned before we have any results to show you. But, we are still certain that it is worth waiting for.

- The time we have had to spend on UK approvals has delayed the start of centres overseas. But, we now have centres in four countries asking parents if their child can join the study. This will help to speed up the end of the trial.
- We have published a paper on the difficulties we have faced. This included advice for our legislators on how to improve things!
- Children can join ICISS as young as 2 months of age or as old as 14 months of age. The first developmental assessment is at age 18 months, so some children stay in the study for 16 months before this is done.
- This means that 78 of the 137 children have finished their 18 month assessment already.
- Children will have their development assessed again at age 3 and a half years if their parents agree. 4 children have now finished this assessment.
- There is no follow up for ICISS between the ages of 18 months and 3 and a half years.
- Because of these difficulties, we have been given some extra money. This has been used to employ an extra member of staff to help get overseas centres up and running. This money comes from the National Institute for Health services Research (NIHR). The money comes to us via our hospital's Research and Development budget.
- We now expect the trial to go on recruiting children until at least 2013 and perhaps 2014. We hope to have 410 children in the trial.
- This means that the last child to enter the trial may not have their 18 month development

assessment until 2014 or even 2016!

Germany

- Professor Osborne has visited Germany twice now to explain to the doctors there how they can take part in the trial. Here is a photo of one of the visits:-



- There have been other visits to Germany to help get approvals for the trial to start there.
- Prof Dietz Rating in Heidelberg has been spending a lot of his time to make sure the trial can start in Germany.
- Both Prof Osborne and Prof Rating hope that this will be the start of more collaboration to study infantile spasms.

Vigabatrin and vision.

- As you know from the trial information sheets, vigabatrin might cause problems with seeing around the edge of your eyesight – a bit like having to see through a pair of glasses and not around the outside of the glasses.
- We told you last year that new information suggests that this problem might not be as common as we had thought. And that we don't think it is likely that it will affect infants treated for only 4 months – as in the ICISS trial.

- Also, researchers in France have studied animals treated with vigabatrin. They suggested that the vision problem may only happen when the infant runs out of tyrosine. They have now shown that adding tyrosine may reduce the risk of damage to animal's eyes.
- But, we still don't know if it is safe or necessary to give additional tyrosine to infants on treatment with vigabatrin for 4 months.

New information about vigabatrin, brain scans and movement disorder.

- Some more papers have now been published about the brain scans of infants treated with vigabatrin. These also show that you can get changes in the pictures of babies brains when they are treated with vigabatrin.
- They have not shown any new information.
- There is no good reason to think that the changes matter. They can disappear even if treatment with vigabatrin continues.
- We have looked to see if infants with unusual movements are more likely to have these brain scan changes.
- The scans of about 28 children have been examined and we will soon know the results.

What else have we been doing?

- In April we published a paper showing what had happened to infants in our previous study when they were 4 years old.
- This paper showed that the difference in development we saw when the infants were 14 months old was still there when they were 4 years old.
- We have also published a paper on the causes of infantile spasms. This paper looked at the causes we found in our last study, UKISS. It suggested ways in which doctors can present the results of trials so that it is clear which causes respond to which treatment.
- We have also written a paper on the effect of the age of the infant

on developmental outcome. And this same paper also looks at the effect of the time from onset of the spasms to the start of treatment.

- This paper has not yet been published, but when it has been published we will let you know the results.
- If you want a copy of either of these papers, please let us know.

Who are we?

- Last year we told you about some of the trial organisers.
- We also have other people on the **Trial Steering Committee**. This committee advises on the best running of the trial. It meets every 3 or 4 months.
- The other people on this committee are:
 - Mrs Catherine Carter who is the parent of a child who took part in our previous trial, UKISS. Catherine is a journalist.
 - Dr Ellie Hancock is a consultant paediatrician – a children's doctor. She works in Woking. She has produced several reviews advising doctors of the best way to treat infantile spasms.
 - Dr Tony Johnson is a statistician. He is an expert on how to study the results of trials of people with epilepsy. He works in Cambridge for the Medical Research Council. He will make sure that we report the results of ICISS properly.
 - Professor Colin Kennedy is a consultant paediatric neurologist – a children's brain doctor. He works in Southampton. He has been active in research in a number of areas including clinical trials and hearing loss.
 - Dr Andrew Lux is also a consultant paediatric neurologist. He works in Bristol. He is responsible for leading the team who are looking at the EEGs of infants in ICISS.
 - Dr Richard Newton is also a consultant paediatric neurologist. He works in Manchester. He has undertaken a number of

research projects and is helping Dr Lux with the EEGs of infants in ICISS.

- Mr Mark Scholefield is another parent whose child was in our previous study, UKISS. He has wide experience of the ethics of research.
- Dr Chris Verity is also a consultant paediatric neurologist. He works in Cambridge. He has been involved in a number of important studies looking at epilepsy in children.

The day to day work of the study is carried out by the **Trial Management Group**. This is lead by Dr Stuart Edwards with help from Mrs Patricia Sheppherd, Mrs Veronica Kerr, and Mrs Kathryn Wheeler.

- Our previous administrator, Jess, who left in 2009 to get married, has had a baby now! We sent her our best wishes up in Yorkshire.
- Veronica took her place and has been with us for one year. She works full time and keeps things going when there are other things for the trial manager to do.
- Patricia has been with us for many years part-time. She spends most of her time with information sent to us from each local hospital about the children in the study. She records this information in the computer so that it is ready to study when the trial finishes.
- Kathryn joined us in June 2010 and is responsible for dealing with all our international centres and getting all their approvals in place so they can enrol into the trial.

Professor Osborne, Dr O'Callaghan and Dr Lux are also part of the Trial Management Group. They visit the trial centre as and when required – someone usually visits twice per week.

Website

- Please don't forget that our trial website can be found at:
www.iciss.org.uk
- If you want to contact us, please use email:
iciss@ruh-bath.swest.nhs.uk

