

PARENT'S NEWSLETTER 2009

ICISS – Continues to make progress

117 hospitals in the UK and 5 overseas are now able to invite parents to take part and 72 infants had started by the end of August.

Dear Parents,

- First of all *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 second in a series of annual newsletters that we will be producing for ICISS parents.
- We hope these newsletters will keep you up to date with the progress of ICISS as it will be some time before ICISS finishes.
- We will try to send you a newsletter every year. Last year only 20 parents were taking part when the newsletter went out so now another 52 parents will see an ICISS newsletter for the first time.
- We will send a copy of last year's newsletter to the 52 parents who will not have had a copy – so you can see what we said. Copies of all parent's newsletters are placed on the trial website so you can get another copy if you want one.
- If there are other things you would like to know, do tell us – and we can include popular items next time.

Timescale.

- We have been badly delayed because of all the difficulties in getting approvals to undertake research. This is much more difficult now than it was during our previous study, UKISS, about 10 years ago.
- As a result we are over 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 results.

- We have just 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 28 of the 72 children have finished their 18 month assessment already. But the other 44 have not yet finished.
- Children will have their development assessed again at age 3 and a half years if their parents agree.
- There is no follow up for ICISS between the ages of 18 months and 3 and a half years.
- Two hospitals in **New Zealand** have already enrolled three infants into the trial and one hospital in **Switzerland** has also enrolled three patients. We expect that other hospitals in Switzerland will join the trial later this year. We hope to start recruiting into the trial in Melbourne **Australia** this month. Other hospitals in Australia will also join when their approvals are in place.
- It has been so difficult getting approvals to start research in the UK that we have had to focus on the UK and have not made as much progress overseas as we would have liked.
- But, because of that we have been given some extra money to employ a new member of staff to help get overseas centres up and running. Ros started work in late July and her presence is already beginning to speed things up. Our other administrator, Jess, left to get married and moved to

Yorkshire. Veronica has taken her place so we have two new faces in the trial office. Patricia has been with us for many years and shows no sign of leaving thank goodness!

- We now expect the trial to go on recruiting children until at least 2012. 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 2013 or 2014!
- But, all these dates may slip if we continue to take longer than expected to enrol infants into the trial – but we will let you know.

New information about 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.
- New information suggests that this problem might not be as common in infants treated with vigabatrin for their infantile spasms as we had thought.
- And anyway 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 have suggested that the vision problem may only happen when the infant runs out of tyrosine. Tyrosine is an amino-acid or building block for protein. Infants usually have enough tyrosine in their diet.

- It is much too soon to recommend treatment with tyrosine because we do not know if this is the cause of the problem in human infants.
- Also, we do not know if adding tyrosine is safe for the infants.

New information about vigabatrin and brain scans.

- Several groups of doctors have now published papers about brain scans of infants treated with vigabatrin.
- They have shown that vigabatrin can cause a change in the pictures we get of babies brains.
- There is no good reason to think that these changes matter. They can disappear even if treatment with vigabatrin continues.
- This affects about 1 in every 5 infants treated with vigabatrin
- We will look to see if we can be sure that these changes do not matter when we look at the results from ICISS.

New information about unusual movements in infants with Infantile Spasms.

- We have had a few infants with infantile spasms who have also had unusual movements.
- We call these “a movement disorder”. This is different from the movements due to the spasms.
- In fact, such funny movements have been known to affect infants with spasms for a long time – but this has never been reported in medical journals.
- The movements may have more than one cause.
- Some may just be the disorganised movements of an infant recovering from a severe illness.
- Other movements may be caused by other diseases – sometimes a disease that has caused the spasms in the first place.
- We are starting to write a paper about this to warn other doctors about the problem.

Website

- 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

Who are we?

We thought that you might like to know who we are!

The people at the trial centre in Bath are the core of the team running the study. There are seven of us.

Professor John Osborne is in charge. He is called the Chief Investigator. But he has retired from NHS clinical work and Dr O'Callaghan who is the Vice Chief Investigator will take over the senior role as Chief Investigator perhaps next year.

Professor Osborne will continue to be heavily involved in the trial – helping to make sure that it is successful. He was the Chief Investigator in our previous trial of treatment for infantile spasms called UKISS.



John Osborne

Dr O'Callaghan is a Consultant Paediatric Neurologist based in Bristol but who also works in Bath.

He has been involved in research in this area since completing his PhD at the University of Bath with Professor Osborne.



Finbar O'Callaghan

Dr Stuart Edwards is the Trial Manager. He was the Trial Manager for our previous study called UKISS. He keeps everything going on a day to day basis. Following our staff changes, he now has three members of administrative staff helping him in the trial office. Previously he was involved in a European collaborative research project studying ECGs in adults – ECGs are electrical tracings of the heart beat.



Stuart Edwards

We will show you photos of some other members of the trial management group next year. We might even put them on the trial website in the meantime – if we can catch them!