

## PARENT'S NEWSLETTER

### ICISS – Began in March 2007

**58 hospitals in the UK are now able to invite parents to take part and 20 infants have started so far.**

#### Dear Parents,

- First of all a big *thank you* for agreeing to take part in ICISS. We hope that taking part in a trial did not add to your problems at a difficult time.
- This is the first in a series of newsletters that we will be producing specifically for ICISS parents.
- We hope these newsletters will keep you and your family up to date with the progress of the study.
- We will try to send you a newsletter every year.

#### About the trial.

The aim of the trial is to see if, with your help, we can improve the prognosis for children with infantile spasms. Can we stop the spasms in more children and if we can, does that help to improve their development?

Before a doctor can enrol a child into this study, we have to get:

- Ethics approval for each centre
- R&D approval (local hospital approval)
- Drug regulatory approval (government approval for the use of the drugs)
- A signed legal agreement with each trust.

It takes a long time to get these approvals, and this is holding up the research – but these requirements are insisted on by the government.

ICISS has been adopted by an NHS network called the *Medicines for Children Research Network* who try to help with these and other problems.

#### Timescale.

- Children can join the study 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 some of the 20 children have finished their 18 month assessment already, but most have not.
- Children who get to age 3 and a half years before the study stops inviting parents to take part, will have their development assessed again – if their parents agree.
- Hospitals are joining the study all the time, so the number of children in the study is going up all the time.
- So far, 175 centres have agreed to take part in ICISS. We may end up with more than 200 worldwide!
- We now have 58 centres approved to take part in the UK so far.
- ICISS started enrolling cases in March 2007, but the number of centres able to invite parents to take part has suddenly started to increase.
- New Zealand are about to start inviting parents to take part and it looks as if Switzerland will beat Australia into third place!
- We expect the trial to go on recruiting children until at least the end of 2010 – perhaps 2011. We hope to have 410 children in the trial.
- This means that the last child to enter the trial may not have their development assessed until 16 months after the end of 2010/11 – so perhaps not until the middle of 2013!

- We will publish the results of the effectiveness of the medicines in stopping the spasms before that – because we will know that 6 weeks after the last child enters the study. Early 2012 perhaps!

#### Website

- Our trial website can be found at:  
[www.iciss.org.uk](http://www.iciss.org.uk)
- There is a special page for parents where you can find the parent's brochure that you are usually given when your child is diagnosed with infantile spasms.
- Did you find the brochure helpful? We hope you did. If you can't get it from the web, ask your local consultant for a spare copy.
- The brochure has been translated into German and Italian. These translations will also be on the website.
- We will soon be adding a page of FAQ's or Frequently Asked Questions, just for parents.
- If you want to suggest adding a question to this list, please contact us by email:

[iciss@ruh-bath.swest.nhs.uk](mailto:iciss@ruh-bath.swest.nhs.uk)

- Please also contact us if you have any difficulty accessing the website.

#### Parent representatives

- Did you know that we have two parents helping us? Both the parents have children who had infantile spasms in the past.
- Both parents took part in our previous trial called UKISS.
- They have read this newsletter before it was sent to you – to make sure it was OK!