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Media Release

Bath doctors discover improved treatment for child epilepsy

Doctors from Bath have discovered an improved way of treating a rare form of childhood epilepsy.

Twelve years ago the same team from the Royal United Hospital and the University of Bath discovered that treating infantile spasms with hormone therapy for two weeks was highly successful.

Now, after a worldwide trial involving 377 infants from a network of more than 160 hospitals in the UK, mainland Europe, Australia and New Zealand, they have found that a combination of hormonal treatment and the anti-epileptic drug vigabatrin is safe and significantly more effective at stopping infantile spasms than hormones alone.

The results, published in the medical journal the Lancet Neurology this week, also showed that giving the combined treatment stopped the spasms a lot quicker.

Dr Finbar O'Callaghan, Consultant Paediatric Neurologist and Professor John Osborne at the RUH, who jointly led the study, said: "Infantile spasms, also known as West syndrome, is a devastating form of infantile epilepsy that is difficult to treat and is associated with a poor outcome.

"This study suggests a new treatment approach that will stop spasms faster and in more children than has previously been achieved with existing treatment strategies. It is therefore possible that this will lessen the long-term damage from this devastating epilepsy on developmental outcomes."

The International Collaborative Infantile Spasms Study (ICISS) is the largest treatment trial of patients with infantile spasms ever undertaken. It was organised and co-ordinated from the Trial Centre in the Children's Centre at the Royal United Hospital (RUH) in Bath in association with the Department for Health, University of Bath.

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Notes for editors:

The International Collaborative Infantile Spasms Study (ICISS)



- Infantile spasms, also known as West syndrome, is a devastating form of infantile epilepsy that is difficult to treat and is associated with a poor outcome.
- Infantile spasms have an estimated incidence of about 0.43 per 1000 live births (thus about 250 children in the UK per year) and occur most often between 3 and 12 months of age with a peak incidence around 6–7 months.
- About half of children affected with infantile spasms already have some neurological problems (brain damage) before the infantile spasms begin. Even if they do not, they can become severely disabled because of the epileptic seizures. The epilepsy can change a normal infant into one of the most severely disabled adults. Autism and severe learning difficulties are common sequelae.
- The infant's development slows, stops and then development is lost following the onset of this devastating disorder. Delayed treatment can lead to worse outcomes.
- Identification of effective, swift acting treatments is therefore important.
- The two treatments that have been most investigated and used for treating this condition are hormonal therapies and vigabatrin.
- In our previous trial, the United Kingdom Infantile Spasms Study (UKISS), our research group compared these 2 treatments and found that hormonal treatments (prednisolone or tetracosactide depot) stopped the spasms in a higher proportion of infants than those infants treated with vigabatrin.
- In UKISS, it was noted that there were some children who, having not responded to the first treatment, subsequently rapidly responded when given the alternate treatment.
- Therefore, our current study called the International Collaborative Infantile Spasms Study (ICISS) set out to test if giving hormonal and vigabatrin therapy in combination would stop the spasms in a greater proportion of infants than those given hormonal therapy alone.
- ICISS involved over 160 hospitals across 5 countries (Australia, Germany, New Zealand, Switzerland and the UK). It was organised and co-ordinated from the Trial Centre in the Children's Centre at the Royal United Hospital (RUH) in Bath in association with the Department for Health, University of Bath.
- The study is led by Dr Finbar O'Callaghan, Consultant Paediatric Neurologist at the RUH and Great Ormond Street Hospital London and Clinical Reader in Paediatric Neuroscience at UCL GOS Institute of Child Health, London. Up until November 2011, the study was led by Prof John Osborne, Consultant Paediatrician at the RUH and Hon Professor of Child Health at the University of Bath. The trial is co-ordinated by Dr Stuart Edwards from the Department for Health at the University of Bath and the Children's Centre at the RUH.
- ICISS enrolled a total of 377 patients with infantile spasms. It is the largest treatment trial of patients with infantile spasms ever undertaken.

- It is also the first trial to assess a combination of therapies (hormonal therapies with vigabatrin) to treat infantile spasms versus the current best treatment (hormonal treatment).
- The results which are published in the medical journal the Lancet Neurology this week show that giving the two treatments in combination was much more successful at stopping the spasms than giving hormonal treatment alone.
- In addition, giving the combined treatment stopped the spasms a lot quicker.
- **Implications of the results:** This study suggests a new treatment approach that will stop spasms faster and in more children than has previously been achieved with existing treatment strategies. It is therefore possible that this will lessen the long-term damage from this devastating epilepsy on developmental outcomes.
- The trial was sponsored by the Royal United Hospitals Bath NHS Foundation Trust and funded by The Castang Foundation, Bath Unit for Research in Paediatrics, National Institute of Health Research, the Royal United Hospitals Bath NHS Foundation Trust, the BRONNER-BENDUNG Stifung/Gernsbach, and University Children's Hospital Zurich.

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