Irish Epilepsy & Pregnancy Register
In conjunction with the UK Epilepsy & Pregnancy Register
Freephone: 1800 320 820
www.epilepsypregnancyregister.ie

The Establishment of a Prospective Epilepsy Pregnancy Registry in Ireland

Introduction & Rationale:

Epilepsy (or recurrent unprovoked seizures) is a common chronic neurological condition affecting 1-2% of the population at some point in their lives. About 25% of people with epilepsy are women of childbearing potential. The interaction between epilepsy, its treatment, and pregnancy is a complex clinical problem. Despite the frequent necessary use of anticonvulsant drugs in pregnancy, little is known of their relative safety both in relation to congenital abnormalities and longer-term effects on development of the child. Older studies of this issue have had many methodological flaws including their retrospective nature, common use of polypharmacy, and lack of control for seizure frequency. In these studies, an adverse foetal outcome was much more likely to be reported than a normal pregnancy. In addition, these studies were performed before the widespread use of folic acid to prevent neural tube defects.

Many new drugs are now available for the treatment of epilepsy, but very little is known about the relative risks and advantages of these compounds in pregnancy. There are now over fifteen anticonvulsant medications (excluding benzodiazepines) available in Ireland for the treatment of epilepsy.

Traditional: Phenobarbital, phenytoin, carbamazepine, sodium valproate.
Recent: Vigabatrin, gabapentin, lamotrigine, topiramate, tiagabine; oxcarbazepine, levetiracetam
Newest: Zonisamide; Pregabalin, Lacosomide, Rufinamide, Eslicarbazepine & Retigabine

In an effort to determine the safest strategies for the treatment of women who are or are planning to become pregnant, there are a number of world-wide prospective pregnancy registries now gathering data in a controlled prospective design. These prospective studies will avoid the reporting bias that has hampered previous studies, and will gather information on the newer drugs. These registries are operating in the United States, Europe, and the United Kingdom. The U.K. Register is being run out of Royal Victoria Hospital in Belfast under the directorship of Dr. Jim Morrow, Consultant Neurologist. Since May 2007, the U.K and Irish Epilepsy and Pregnancy Registers have formally amalgamated. The ongoing running of each register remains unchanged; however the anonymised data from both registers will be amalgamated every 6 months.

The Irish Epilepsy and Pregnancy Register is based in the Clinical Research Centre, at Beaumont Hospital under the guidance of Dr. Norman Delanty, Consultant Neurologist. Dr. Delanty and Brenda Liggan (epilepsy research nurse managing the register) have already visited the U.K. unit in Belfast, and close logistic and academic ties have been agreed between Dr. Morrow and Dr. Delanty.

This study will be a unique opportunity to study the effects of anti-convulsant drugs in pregnant women in the whole of Ireland. The importance of this study will be to include all women in Ireland with epilepsy whom become pregnant and to follow the physical and mental development of the children. The Register will be set up to systematically survey all pregnancies in women with epilepsy in the whole of Ireland. Every GP, obstetrician, physician, and neurologist in the country will be given information and a free phone number, and patients will then be invited following informed consent to enrol by telephone in the Register at the time of diagnosis of pregnancy. The outcome of the pregnancy will then be reported to the Register by the GP, three months following term. The outcome of pregnancy may also be assessed at intervals after the expected date of delivery to follow neurodevelopment of the child.

Aims:

Primary objectives

1. To establish an ongoing nationwide prospective registry of epilepsy and pregnancy in the Republic of Ireland, which will have close links with the U.K. registry based in Belfast.
2. To establish the relative safety of the individual antiepileptic drugs with reference to major malformations in the offspring of women with epilepsy.

Secondary objectives

1. To establish whether seizure frequency is related to adverse outcome in pregnancy.
2. To establish the rate of preconceptual folic acid administration in women with epilepsy and whether this beneficially affects outcome.
3. To educate people about epilepsy and pregnancy by giving pre-conceptual, pregnancy and post-pregnancy advice (related to epilepsy).

Methods:

Physicians and patients will be encouraged through a variety of means (educational brochures, posters and advertising) to report to our central office at the Clinical Research Centre, Beaumont Hospital (via freephone **1800 320 820** or download registration forms from www.epilepsypregnancyregister.ie). The following information is then obtained:

- Patient details
- General date of delivery
- Estimated date of delivery
- Antiepileptic drugs and dosage
- Folic acid prescription and dosage
- Seizure type and frequency

Three months after the estimated date of delivery the patient's GP is sent a further questionnaire asking for obstetric history, present and previous, and details of the outcome of this pregnancy. If there is any abnormal outcome, specific details will be requested. Future neurodevelopment of the child may be assessed, if appropriate.

Each woman will fill out a written informed consent sheet. All information will be treated with the strictest confidentiality. Data from the Register may be evaluated by health professionals who may have been involved in the ongoing care of the registered woman (e.g. paediatricians, clinical geneticists, epilepsy nurse, and neurologist). Complete anonymised data may be looked at by regulatory authorities, pharmaceutical companies and U.K. Epilepsy and Pregnancy Register personnel.