



Freephone: 1800 320 820
www.epilepsypregnancyregister.ie

PATIENT INFORMATION SHEET

A REGISTER IN IRELAND TO DETERMINE THE SAFETY OF THE ANTI-EPILEPTIC DRUGS IN PREGNANCY

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of Study

We are conducting a study to determine which of the drugs used to treat seizures (or epilepsy) are the safest in pregnancy. The reason for doing this is that whilst there is some evidence that the older anti-epileptic drugs (AEDs) can rarely affect foetal development, there is very little information on the safety of the more recently introduced AEDs. We have therefore set up a Register in Ireland for comparing the safety of all available AEDs. To do this we propose to collect information on the outcome of all pregnancies occurring in women with seizures (or epilepsy), whether or not AEDs are being taken. As a women with seizures (or epilepsy), who has become pregnant, you have therefore been chosen to take part in the study.

It is however, up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

If you decide to take part the information we initially need forwarded to the Register includes demographic details (including name and date of birth), details on your seizures (or epilepsy), past and present AED intake, and expected date of delivery. We need to know your name and date of birth as at intervals after the expected date of delivery we need to gather information on the course and outcome of this, and any other previous pregnancies, if appropriate. This information will be collected from your GP and any other doctors who may have been involved in your care during this pregnancy (for example paediatricians, clinical geneticists). All information will be sent to us at the Register, which is based at the Clinical Research Centre, Smurfit Building, Beaumont Hospital, Dublin 9.

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Since May 2007, the U.K. Epilepsy and Pregnancy Register and the Irish Epilepsy and Pregnancy Register have formally amalgamated (joined together). The ongoing running of each Register remains unchanged; however the anonymised data from both Registers will be amalgamated (joined together) every 6 months.

All information is strictly confidential and will not be made available by us to anyone other than those who are directly involved with your care (e.g. neurologist, epilepsy nurse, paediatricians, clinical geneticists). Complete anonymised information may be reviewed by regulatory authorities, pharmaceutical companies and the U.K. Epilepsy and Pregnancy Register personnel. In addition, any results from the study will be presented only in a way that does not allow you, or anyone else who takes part in the study, to be identified.

If you decide to take part, you will not be required to make any additional visits to any clinics or to have any additional tests or procedures. If you decide to take part we, at the Register, will also not be in direct contact with you following initial registration. However, if you wish to contact us for any further information, contact details are as given at the bottom of this page.

Thank you for taking the time to read this, and for considering taking part in the study.

Contact Details: Dr. Norman Delanty, Consultant Neurologist, Beaumont Hospital, Beaumont, Dublin 9.

Or

Brenda Liggan, Epilepsy Research Nurse, Epilepsy and Pregnancy Register, Clinical Research Centre, Smurfit Building, Beaumont Hospital, Dublin 9.

**FREE PHONE TELEPHONE NUMBER:
1800 320 820**

Or

Download registration forms from www.epilepsypregnancyregister.ie

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