

Study Title:

Research project to obtain information about Demyelinating Disease of the Central Nervous System in Childhood being undertaken from September 2009 – September 2012

Inflammatory Demyelinating diseases are a group of illnesses which affect the coating (myelin) of nerve cells in the brain and spinal cord, and can occur, though they are rare, in childhood and adolescence. Many children recover well from a demyelinating event which may cause muscles to become weak or senses like vision to become poor. However, some have longer term problems or may eventually be diagnosed with Multiple Sclerosis (MS). At the moment, we do not know how often these conditions occur in children in the UK and Ireland, and we can't always predict the outcome for a child who is affected. Along with other studies by our children's demyelination research group (www.childdemyelination.org.uk)*currently under development, this population study attempts to address these gaps in our knowledge.

What is the purpose of the research project?

This study would like to:

- (1) Find out how many children under the age of 16 years are affected by a new demyelinating event (incidence) in the UK and Ireland.
- (2) Find out what happens to children over time, for example how many children have a disability or a second episode.
- (3) Describe treatments currently being used in the UK and Ireland.
- (4) Find out whether it is possible to predict which children will later be diagnosed with Multiple Sclerosis.

How will the research be carried out?

We will do this research with the help of:

- **The British Paediatric Surveillance Unit (BPSU)** which studies rare disorders of childhood.
- **The British Ophthalmological Surveillance Unit (BOSU)** which studies rare eye disorders in children and adults.

This type of research is called surveillance. Doctors in the UK and Ireland who are treating a child with this condition during the period of the study are identified by the Units. They will then be sent a questionnaire which is designed to answer the research questions.

Will information about children taking part in the research project be kept confidential?

The information in the questionnaire which is returned to the units by the doctors is anonymised, so that all personal information about patients will remain confidential

The **Research Ethics Committee** and the **National Information Governance Board (NIGB) Ethics and Confidentiality Committee** have approved our study.

Have parents and patients been involved in this study?

We have taken advice from patients and parents of children with these conditions to help us decide what information is important to collect. Many families are unhappy that there is so little information about these diseases and their outcomes. They considered that this study would help to raise doctors' awareness of how important these conditions are in children. The MS Society is supporting our study.

What are the benefits from the study?

We will find out how many children have a demyelinating event for the first time each year in the UK and Ireland, what kind of treatments they receive and how well they do afterwards. This will help us to understand the importance of these diseases and enable future studies to look in more detail at improving treatments and outcomes.

Understanding the treatments:

Because the condition is so rare, there is not much information about the medicines which are most useful for children and they are often given the same ones as for adults

What will happen to the results of the research study?

Results of the study will be published in a medical journal, on the BPSU website and on the website of the MS Society (see below).

Who is funding the study?

The MS Society (www.msociety.org.uk) and Action Medical Research (www.action.org.uk).

If you have any questions about this study, then please contact:

- Dr Michael Absoud: MS Society Research Fellow, Birmingham Institute of Child Health
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- Dr Evangeline Wassmer: Consultant Paediatric Neurologist, Birmingham Children's Hospital
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You may also wish to look at further information on these websites:

- **British Paediatric surveillance unit BPSU:** www.bpsu.inopsu.com
- **Multi Centre Research Ethics Committee (MREC):**
Information available from www.dh.gov.uk or ring NHS direct 0845 4647
- **NIGB Ethics and Confidentiality Committee:**
Information available from www.nigb.nhs.uk/ecc or ring 0207 633 7052

