Pregnancy Registry Trial – Gilenya (fingolimod)

What is the title of the study?
The Multi-National Gilenya® Pregnancy Exposure Registry in Multiple Sclerosis

Which institution is responsible for the study?
Novartis Pharmaceuticals

What's this study about?
The aim of the study is to collect and evaluate safety data on the effects of women taking Gilenya (fingolimod). Safety data will be analysed for the following periods:

- immediately before (up to 8 weeks before last menstrual period)
- during pregnancy
- associated pregnancy outcomes in terms of the health and development for both the mother and baby for approximately one year afterwards

How will this help people affected by MS?
This registry will provide safety information on the effects of fingolimod on pregnancy and the health and development of the foetus and infant. Currently the data available are too limited to draw any conclusions about the effects of fingolimod in pregnancy and the outcome of the baby.

What will participants be asked to do?
The patients will need to sign an Informed Consent form if they agree to take part in the study.

Participating in this registry does not require the patient or her baby to take part in any additional medical visits or medical procedures above their routine care. The Registry doctor from one of the National Coordinating Centres (see below) will collate the information from the patient's routine GP/clinic visits and medical records at specified timelines. The patient will need to sign a further Consent Form once the baby is born. Data will be collected for approximately one year after the baby is born. No additional tests or visits to the mother or baby will be required.

Who can take part?
Any female with a diagnosis of MS who is currently pregnant and who took fingolimod during the pregnancy or up to 8 weeks before her last menstrual period. Males who are on fingolimod and whose partners become pregnant are not eligible for enrolment.

Who is conducting the research?
Novartis Pharmaceuticals in association with the Contract Research Organisation Quintiles Outcome.

When can I take part in this study?
The Gilenya Pregnancy Registry is now recruiting and will be run for six years.

Where is this research taking place?
Any eligible and consenting patient anywhere in the UK can enrol in the registry. Quintiles Outcome is the Research Organisation conducting the study on behalf of Novartis Pharmaceuticals. There are two National Coordinating Centres in the UK which are situated in Norwich and Newcastle. The patient's own doctor (this could be GP, neurologist or obstetrician) will refer the patient to one of the National Coordinating Centres who will

contact the patient's doctor in order to collect the relevant data from them. Please note the patient will not be required to travel to the National Centres.

Who has reviewed this study?
This study has been approved by the relevant UK Ethics Committees.

Interested?
If you would like to find out more about this study and would like to receive a participation information sheet, please contact your doctor with this information.

Please note that enquiring about participation does not commit you in any way.