MSBase/MGBase Registry Global Cohort Study of Multiple Sclerosis (MS) and other Neuroimmunological Diseases (NIDs)

Participant Information Sheet

You are being invited to take part in an international research registry of patients with neuroimmunolgical diseases including multiple sclerosis (MS) neuromyelitis optica (NMO), anti-MOG and myasthenia gravis (MG). Before you decide whether you would like to take part it is important that you understand why the research is performed and what it will involve. Please take time to read the information carefully. Ask us if there is anything that is not clear or if you would like more information.

Part 1 of this information sheet tells you about the purpose of this study and what will happen if you decide to take part. Part 2 gives you some more detailed information about what will happen in the study. Take time to decide whether or not you wish to take part and feel free to discuss the project with a relative or friend or health care worker.

.

PART 1

What is a research registry?

A research registry is also known as a research database. It is a collection of information about lots of people, often who all have the same health condition. The data is stored to allow researchers to learn more about a population of patients and their condition.

What is the purpose of the MSBase/MGBase research registry?

The data collected in the MSBase/MGBase Registry will be used in research that aims to improve the quality of care for patients with neuroimmunolgical diseases.

The MSBase/MGBase observational registry aims to:

- collect clinical information from a large number of patients with diagnosed neuroimmunological diseases and people who have had symptoms that are suggestive of MS,
- enable researchers to observe the effects and safety of current and future treatments,
- enable researchers to document disease outcomes in different parts of the world.

Why have I been chosen?

You are being asked to take part because you have been diagnosed with a neuroimmunolgical disease such as multiple sclerosis (MS) neuromyelitis optica (NMO), anti-MOG and myasthenia gravis (MG) or you have experienced an episode of symptoms that is suggestive of MS.

Do I have to take part?

It is 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 choose not to take part or withdraw at a later stage, this will not affect the care you receive in any way.

What will happen to me if I take part?

If you agree to take part in the study you will be asked to sign a consent form to record this decision. You will continue to have routine clinical visits and assessments at the hospital with your normal doctor and will be given treatment as usual. The only thing that will change is that the normal information collected by the doctor at your appointments will be entered into the MSBase Registry. Your treatment and management will continue as normal at the hospital with your doctor.

The information from your medical records that will be in the registry will be coded so that no one outside of _____ is able to know your name or who you are. There is no identifying information contained in the registry. All your information will be treated confidentially and we will follow all privacy rules. Everyone involved in this study will keep your data safe and secure

Who is organising the study?

The sponsor of the MSBase/MGBase registry is the MSBase Foundation Ltd, a collaborative, international not-for profit organisation with head-offices based in Australia.

How long will the study last?

MSBase/MGBase Registry will continue as long as funding is available to manage the project. We would plan to collect data from your record and hold it for as long as the registry exists or until you told us you no longer wanted to be involved. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have in the registry

If I agree to take part, what am I agreeing to do? – A summary

Taking part in this project means completing a consent form and agreeing to information from your medical records being entered into a worldwide database on an ongoing basis and for an indefinite period of time.
No one will be able to identify you from the data that is put into the registry.
You will not have to attend any extra hospital appointments or have any extra tests or investigations or treatments.

PART 2- This section describes in more detail how the research will be conducted and how your data will be collected and used.

How will information about me be used and what information about me and my condition will go onto the MSBase/MGBase Registry?

The MSBase/MGBase Registry works by staff at_____ entering your details into data-collection software (either a system called the "MSBase Data Entry Software", or "MSBase iMed data collection software and visualisation tool"– both of which have been designed specifically for MS and other NIDs care). These software can only be accessed by your care team and the local research team at _____ .The systems are fully password protected. In some sites, this information is already collected in existing secure hospital software, so can automatically be transferred into the "MSBase iMed data collection software and visualisation tool". Information from either of these systems is then sent electronically to the MSBase central registry secure storage location which is hosted by Microsoft Azure Servers in Australia which complies with all regulatory requirements. The MSBase Registry Operations team and researchers who use of the MSBase Registry do not need to know who you are and so they will only be able to see your coded record and medical information. We will take every possible precaution to ensure that your personal information is kept private, safe and secure.

If you have MRI scans as part of your standard care we will ask for your consent for these scans to be sent to the MSBase imaging repository. It will not be possible to identify you by the codified scans that are transferred to the MSBase imaging repository.

The information that will be seen by the people who use the MSBase Registry will not identify you.

This data includes:

- Month and Year of birth,
- Details of your medical history,
- Results of any tests and investigations like MRI scans, spinal fluid tests or blood tests,
- Results of your neurological tests and examinations such as the Expanded Disability Status Scale (EDSS),
- Information about any family history of neuroimmunolgical diseases like MS,
- Information about the medications that you take for any condition,
- Medical conditions including adverse and serious adverse events

Once your coded information reaches the Registry it may be used for current and future studies of MS/NIDs by participating MSBase neurologists/researchers. These groups of people will not be able to identify you from this data. All required approvals for future research carried out in the U.K. using MSBase data will be sought from the appropriate bodies.

Codified data collected on the registry can be sent securely to approved MSBase members for research projects. MSBase members must submit a data request to access data. Data requests are reviewed by the MSBase Scientific Leadership Group. The requester must sign a data use agreement and they must follow all rules about keeping your information safe. You would not be able to be identified from this data.

Will my taking part in this research be kept confidential?

Medical records that identify you, and the consent form signed by you, will never be given to the Registry. However, to make sure that the study is being done properly, these documents may be inspected by authorised persons from UK research regulatory authorities, from _____ or through an independent audit if requested by the MSBase Scientific Leadership Group. If this happens, the people looking at your data at _____ will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will ever be disclosed outside _____ .

Where can I find out more about how my information is used?

The MSBase Foundation has a Data Protection Officer (DPO) who is responsible for how your codified medical data is processed and treated but because your identifying information is removed and your record is pseudonymised before it reaches the MSBase Foundation, the MSBase DPO will not be able to assist you with any questions relating to your personal information. They would not be able to look you up in the Registry and for privacy reasons they would not want to collect any personal information from you either over email or over the phone. If you have any questions about how MSBase will use your information, you should contact one of the research team members from _____ whose details are listed at the end of this information sheet. You can also access the Registry's Privacy Notice at _____ . You are able to review some general information about how patient information is used for health and care research at https://www.hra.nhs.uk/information-about-patients

What are the possible risks and benefits of taking part?

Possible Risks: The MSBase/MGBase Registry study is purely observational. This means that there is no change to your care or treatment as a result of taking part. The data collected for the registry is either taken from your standard healthcare record and may also collected as part of your routine visits to your local clinic.

No system of data storage is 100% secure and so there is always a risk that data protection could be breached. However, we have taken every possible step to ensure the security and confidentiality of your information.

Possible Benefits: There are no direct benefits to you for taking part in this study. We hope that the information collected for the MSBase Registry will help us to better understand neuroimmunolgical diseases such as multiple sclerosis (MS) neuromyelitis optica (NMO), anti-MOG and myasthenia gravis (MG) and lead to improvements in quality of care.

What will happen if I withdraw from the study?

You are free to withdraw from the study simply by telling us your wishes. You do not have to give a reason for withdrawing and this would not affect your care in any way.

If you want to withdraw at any time after you have filled in the consent form, you will need to contact us on one of the numbers or emails at the end of this information sheet.

If any data has already been provided to the registry before you tell us that you want to withdraw, that data will remain in the registry but no more data will be added.

What if something goes wrong?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you can contact the Principal Investigator at _____ directly. Their contact details are at the end of this information sheet.

The normal NHS complaints mechanism is also available and the _____ complaints team can be contacted on _____.

You can also avail of independent advice from Select Relevant Service on _____.

Will I be paid to take part in this research?

You will not be paid to take part in this study.

Will _____ or MSBase be paid for my data?

The MSBase Foundation may provide funding to _____ but this is to help with the costs of data collection only.

Reports from the Registry may be provided to drug companies so that they can better understand the effectiveness and safety of their medicines. MSBase receives funds to cover the cost of providing these reports.

What will happen to the results of the research?

Results will be presented at scientific meetings around the world, published in medical journals or magazines and online.

Any results or outcomes of the research will not identify you individually.

If you would like to read the published results, they will be available on the public access version of the MSBase website at: www.msbase.org under the “Data and findings” section.

Who has reviewed the study?

This study has received ethical approval in the UK from _____ . Local approval to carry out this research at _____ has been confirmed by the Principal Investigator named at the end of this information sheet.

The project will be carried out in accordance with the National laws and regulations of _____. A global Scientific Leadership Group of leading MS specialists that reports to the MSBase Foundation will closely monitor and analyse the data collected through the database.

Contact for Further Information

If you have any questions about this research, please feel free to contact us on the details below.

Principal Investigator Name: Telephone: Email:
Research Nurse/secondary contact Name: Telephone: Email:

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET AND FOR CONSIDERING WHETHER TO TAKE PART IN THIS RESEARCH.