Participant Information Sheet for Carers

**Study title**

**Molecular Imaging of Synaptic Loss in** **Multiple System Atrophy (MSA)**

**Short Title:** Synaptic Loss in MSA

**Chief Investigator: Prof Marios Politis**

**Sponsor: University of Exeter**

**Invitation**

You are invited to take part in a research study as a carer of a relative/spouse/friend/patient (hereinafter “the patient”) who has a diagnosis of Multiple System Atrophy (MSA). You are invited to take part in a small part of this research study. A separate information sheet will be provided to the patient. If you choose not to take part in this research study, the patient can still be invited to participate.

Before you decide, it is important to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish. If anything is unclear or if you would like more information, please get in touch with one of the study team. Take your time to decide whether or not you wish to take part.

Thank you for reading this.

**What is the purpose of the study?**

Multiple System Atrophy (MSA) is a chronic neurological condition that progresses over time. MSA causes symptoms such as slowness of movement and stiffness, lack of muscle control or coordination of voluntary movements, and urinary problems (dysfunction). Patients with MSA are found to have a build-up of a protein, called alpha-synuclein, in several areas of their brain. This protein collects close to the brain cells, which provide support and insulation to nerve cells (neurons). The exact way (mechanism) that alpha-synuclein accumulation leads to the gradual breakdown of neurons, causing the symptoms of the disease, is still unclear. However, we know that even before these cells die there is a loss of synapses (the structure which allows brain cells to send messages to other brain cells and across the brain) and a decrease in the metabolism of glucose (sugar), which is used as a measure of brain activity. By use of a special scan, called Positron Emission Tomography (PET), it is possible to determine the loss of synapses (synaptic loss) and the decrease of glucose metabolism. We can do this by the use of very small amounts of radioactive substances called tracers, which are injected through a cannula (tiny tube) into your vein, the tracers attach themselves to specific targets in the brain that we wish to study. Then by using another brain scan called Magnetic Resonance Imaging (MRI) it is possible to measure brain structures and the integrity of connections (how well the connections work) between different areas in the brain.

In this study, we aim to use PET imaging specific for measuring synapses and glucose metabolism, to investigate their role in disease progression in people with MSA. We will also use MRI imaging to evaluate the structural and functional changes in the brain in patients with MSA. Furthermore, we will explore the relationship between synaptic loss, glucose metabolism, and clinical features in people with MSA. Our findings will provide a deeper understanding of the brain changes specific for the disease, which will help us track the progression of MSA. More importantly, this study will help with the discovery and development of new medications aiming to delay progression of symptoms caused by MSA.

**Why have I been invited?**

You have been asked to participate in a small part of this research study because you are the carer of a patient that has been found to have MSA.

For this study, we intend to enrol 20 participants with this condition. This would allow us to gain significant information about the mechanisms underlying this disease. This research will take place in London. If you are not from London, travel and (in case it is necessary), accommodation will be arranged for you and the patient by the research team.

**Do I have to take part?**

No, 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 for carers. If you have agreed to take part you are still free to withdraw at any time without giving any reasons and this will not affect the standard of hospital care you receive or your legal rights. Any identifiable data or tissue that has been already collected with consent from the patient would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out.

**What is involved in this study if I take part?**

If you agree to take part in this study, there are a few things we would like you to consider please. We will ask you and the patient to attend the Imperial College Clinical Research Facility at Hammersmith Hospital for the clinical assessments to be undertaken. The Imperial College Clinical Research Facility at Hammersmith Hospital Campus (Du Cane Road, W12 0NN, London), provides comfortable clinical accommodation for study participants, covering both long-term in-house monitoring as well as day visits. It is equipped to cater for research studies from across the range of medical disciplines.

All appointments will be arranged on a weekday. All transportations to and from the research site, for you and the patient, if needed, will be arranged by us.

Your participation will involve one (1) baseline visit at the start of the study and then one (1) visit after 12-14 months (follow-up visit).

The patient will undergo additional visits, the full details of which are outlined in the participant information sheet for patients. The patient will be provided with the participant information sheet for patients and will independently consent to taking part in this study.

**Details of what will happen at each visit is outlined below.**

**Visit 1: Screening and clinical assessment**

At the first visit the patient will undergo screening and clinical assessments that are required for the study. The visit will last approximately 3 hours and will take place at the NIHR Imperial Clinical Research Facility in London.

During this time, you will firstly have the opportunity to discuss the study with the doctor, ask any questions you may have and then, if you agree to take part into this study, you will be asked to sign the consent form, a copy of which will be given to you for your records. No research-related activity can take place until you have given your written informed consent.

If the patient also independently consents to take part in the research study, some clinical scales (questionnaires and tests) will be administered during this visit to assess the presence of symptoms related to how the patient moves (motor symptoms), think (cognitive symptoms), and behave (symptoms related to mood, sleep, and quality of life). You will only be asked to participate in two of these questionnaires, called the Unified Multiple System Atrophy Rating Scale and the Neuropsychiatric Inventory. These questionnaires assess if the patient experiences motor symptoms and non-motor symptoms and, if so, assess to what degree these symptoms affect the patient. Collecting information from you allows us to collect more precise information. Each questionnaires is composed of a few questions and takes about twenty minutes in total to complete.

The patient will be asked to undergo additional clinical assessments and procedures during the visit, the full details of which are outlined in the participant information sheet for patients. During these additional clinical assessments and procedures, you will be invited to accompany the patient.

All clinical assessments will be performed by a qualified doctor with previous clinical and research experience on MSA-P.

**Visit 2: Follow-up clinical assessment**

For Visit 2 we will ask you to come again with the patient after 12-14 months, to repeat the clinical assessment. The procedures will be the same as in visit 1.

**Please note:**

You can contact the study team at any time if you have any questions which arise in between the study visits. You can find the contacts of the study team at the bottom of this document if you need to contact us.

If you experience any distress during the study, we will endeavour to provide you the support you may require.

Please find below a summary of the study visits for this study.

**Summary of Visits**

|  |  |
| --- | --- |
| **Visit 1****Baseline****(Imperial Clinical Research Facility)** | **Visit 2****Follow-up – approximately 1 year later****(Imperial Clinical Research Facility)** |
| - Two clinical questionnaires:* Unified Multiple System Atrophy Rating Scale (UMSARS)
* Neuropsychiatric Inventory (NPI)

Duration of the clinical questionnaires: approximately 20 minutesTotal duration of the visit approximately 3 hours | - Two clinical questionnaires:* Unified Multiple System Atrophy Rating Scale (UMSARS)
* Neuropsychiatric Inventory (NPI)

Duration of the clinical questionnaires: approximately 20 minutesTotal duration of the visit approximately 3 hours |

We will reimburse transportation to and from the hospital for you and the patient, if needed. You will be provided with refreshments throughout your visits. Please keep any travel tickets or parking receipts, as you will need to provide those to the research team in order to receive a refund.

**What are the possible benefits of taking part?**

The research study does not provide any direct benefits to participants. However, the knowledge acquired from this study will improve our understanding of Multiple System Atrophy (MSA) and may help us to provide the means for the development of better drugs for this disease.

**What if something goes wrong?**

The University of Exeter has insurance cover in place to cover its legal liability for injury or illness arising from this study. If you are following a private insurance scheme, you should notify your insurer that you are taking part in this study. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. In case you are harmed due to negligence during or as consequence of procedures carried out by NHS staff, for example because of blood sample collection, NHS indemnity scheme will apply.

**Will my taking part in this study be kept confidential?**

The University of Exeter is sponsor for this study based in the United Kingdom. We will be using information collected in order to undertake this study and will act as the data processor for this study. This means that we are responsible for looking after your information and using it properly.

Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter’s lawful basis to process personal data for the purposes of carrying out research is termed as a ‘task in the public interest’. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University’s processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University’s Data Protection Officer by emailing dataprotection@exeter.ac.uk or at [www.exeter.ac.uk/dataprotection](http://www.exeter.ac.uk/dataprotection). If you have any concerns about how the data is controlled and managed for this study then you can also contact the Sponsor Representative, Pam Baxter, Senior Research Governance Officer, whose details are at the end of the information sheet.

There are two possible scenarios

(1) Enrolment from NHS clinic: patients enrolled at the Royal Devon & Exeter NHS Foundation Trust (RD&E), where the identifiable information will be transferred to the University of Exeter

(2) Enrolment from non-NHS source: Patient enrolled at the University of Exeter, where the identifiable information will not be transferred to the RD&E Trust.

The University of Exeter will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Exeter or regulatory authorities may look at your medical and research records to check the accuracy of the research study, where it is relevant to you taking part in the research. The RD&E Trust will securely pass these details to the University of Exeter along with the information collected from you. The only people at the University of Exeter who will have access to information that identifies you, will be people who need to contact you regarding the research study or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

In the unlikely event that you will lose your capacity during the course of the study, you would be withdrawn from the study. All identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to you.

The Imperial Clinical Research Facility is part of Imperial College Healthcare NHS Trust, and we rely on several NHS systems and procedures to support our research. To include you in this study we will need to register you at Imperial College Healthcare NHS Trust and record minimal information about you in the Trust’s medical records system.

Healthcare records may be in paper or electronic format and will typically include laboratory test results, radiological imaging (e.g. ultrasound scans, X-rays, MRI etc), clinical notes, routine observations, prescription charts (a list of medicines given to you) and other study-specific information which is collected as part of the research. Such information may be valuable to support your normal health care now, or in the future. If you are not already an NHS Trust patient, we will need to register you.

Although information collected as part of this study will be available in your medical records, a duty of confidentiality applies, and staff within the NHS may only access your records if they have a legitimate and lawful reason to do so. If you have any concerns about this, please speak with your study doctor.

The research study staff will keep a copy of your signed informed consent form indefinitely, for as long as coded information is in use, but no other information that could directly identify you will be stored in any study-related documents after 10 years.

The University of Exeter will keep identifiable information about you from this study for 10 years after the study has finished. We will use this information for research purposes only.

You can find out more about how we use your information by contacting the Chief investigator Prof. Marios Politis (m.politis@exeter.ac.uk) or the study team:

Study Doctor:

Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator:

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

All employees working in the NHS are bound by a legal duty of confidence to protect personal information and therefore any information you give during this study will be kept confidential. Should we be concerned about your health or wellbeing we may discuss this with your clinical care team/GP.

**What will happen to the results of the research study?**

The results of the research are likely to be published in a peer-reviewed scientific journal. You will not be identified in any report/publication.

If you wish, feedback will be sent to you from the research doctor with the results, which will be in a manner understandable to a non-medical person.

**Who is organising and funding the research?**

The study is funded by Invicro London (Imanova). The funders have no commercial interest on this study. The University of Exeter is the Sponsor of the study, contact details of the Sponsor Representative are below.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the <XXX> Research Ethics Committee. It has also been reviewed by the Health Research Authority (HRA) in order to obtain HRA Approval. The study is also assessed by each NHS Trust involved with the research in order to obtain Capacity and Capability Approval at local level.

**Contact details for Further Information**

If you have any questions or there is anything you wish to discuss please contact the Chief Investigator Prof. Marios Politis (m.politis@exeter.ac.uk) or the study team:

Study Doctor:

Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator:

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor Representative:

Ms Pam Baxter
Senior Research Governance Officer
University of Exeter
Research Ethics and Governance Office, Lafrowda House, St Germans Road, Exeter, Devon, EX4 6TL Tel: 01392 723588

<http://www.exeter.ac.uk/cgr/researchethics/>

The study team is located at the London Offices, University of Exeter College of Medicine and Health, Translation and Innovation Hub, Central Working 4th Floor, 84 Wood Lane, White City, London, W12 0BZ.

If you agree to participate in this study, please sign the consent form. You will be given a copy of the information sheet and a signed consent form to keep for your records.

Thank you for your interest in the study and for reading the Information Sheet