

Version 1.2

16/09/2015

**INFORMATION FOR VOLUNTEERS**

**Detection of pseudoprogression using CT perfusion in patients with Glioblastoma Multiforme (GBM) post-treatment**

You are being invited to participate in a research study which will involve a special CT scan called a CT perfusion scan following your treatment to look at blood flow in your brain. The aim of the scan is to identify any false increase in size (pseudo-progression), which is an increase in the non-tumor enhancing area seen on the post-operative Magnetic Resonance Imaging (MRI) scan. Before you decide whether to participate, 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 feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and GP if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

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

Imaging is very important for diagnosing and following-up patients with treatment is crucial. We intend to monitor your brain tumour (Glioblastoma Multiforme) after your treatment using both CT and MR perfusion. The early identification and treatment of tumor increase (progression) following treatment procedures may reduce quality of life; therefore it is crucial to separate patients with true tumor progression from those with pseudo-progression or false increase in size.

The current or routine practice is to follow up GBM (brain) tumor by MRI, which includes a special MRI scan to look at blood flow. This is current clinical practice at the moment. Sometimes MRI is not suitable for looking at blood vessels and blood flow in brain tumours and an alternative scan such as perfusion CT is more useful for looking at these vessels. The CT perfusion scan allows Doctors to accurately measure tumour physiology and calculate blood flow and blood volume in your brain. The research we hope to conduct with hopefully give us a better insight into whether your treatment has successfully reduce the tumor growth and moreaccurately assess if thetumor needs further treatment, more accurately than the method being currently used i.e. MRI (current practice)

**Why am I being invited to take part?**

We are inviting you to take part in the study because you have undergone treatment for a GBM tumor. You have been selected for this particular study as your initial scan does show progression but you do not exhibit tumor progression clinically, suggesting you have pseudo-progression.

**Do I have to take part?**

Your participation in this study is completely voluntary, it is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at the Walton Centre will continue and nothing will change. You are free to withdraw from the study at any time without explanation.

**What will happen if I take part?**

You will undergo a single CT perfusion study this extra to the current practice and will conduct at the same time that you attend for an MRI scan to monitor your tumor, which is current clinical practice. This is just like a CT scan and a dye will be injected into your vein via a cannula. The whole CT Perfusion study will take approximately 15-20 minutes extrain the radiology department.

**What are the possible disadvantages and risks of taking part?**

The main disadvantage of CT is the radiation dose. This dose will be kept as low as possible. The dye injected into your vein will be iodinated contrast. There are risks associated with iodinated contrast such as anaphylaxis (breathing difficulty), allergic reaction and renal problems, which will only occur if there is pre-existing kidney disease. However these effects are extremely rare and precautions will be taken to reduce the risk of these side-effects from occurring.

**Are there any benefits in taking part?**

There are no direct benefits to the individual taking part in the study. However, the research data acquired will enable a more rapid assessment and differentiation of true tumor progression (true increase in size) from pseudo-progression (false increase in size), which we hope will assist in the diagnosis and treatment of future patients with GBM and better distinguish normal brain tissue and what is new tumor increase and better decide whether further treatment to patients who increase in tumor size is actually due to pseudo-progression.

**What if I am unhappy or if there is a problem?**

If you are unhappy, or if there is a problem, please feel free to let us know by contacting the research team on 0151-525-5540 and we will try to help.

**Will my participation be kept confidential?**

We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be safely stored. Only researchers directly involved with the study will have access to your information. It will not be shared with or given to anyone.

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

The results of the research study will be presented at research meetings and published in scientific literature, so that other researchers can also benefit from the sharing of anonymised information. We are very happy to supply you with our final results at the end of the study. You will not be identifiable from the results presented.

**What will happen if I want to stop taking part?**

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way. You will still have all the benefits that you would otherwise have at the Centre. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this hospital will be unaffected.

**Who can I contact if I have further questions?**

Please feel free to contact the Principle Investigator **Dr. K. Das (Consultant Neuroradiologist)** and the study team.

If you have any questions that you would like to ask before, or at any point in the study, you may contact any of the following:

1. Neuro-Oncology link Nurse specialist-01515295642
2. Dr. K. Das’ Secretary-01515295614
3. Dr. M. Jenkinson’s Secretary-01515295683
4. Mr. A. Brodbelt’s Secretary-01515295679
5. Mr. T Kelly CT Research Radiographer-01515540

**This proposal has been reviewed and approved by the ethics committee at the Walton Centre and North West NHS ethics committee, which are committees whose task it is to make sure that research participants are protected from harm.**