Information sheet for families/friends

Lay title:	A pilot study of the MAnagement of Systolic blood pressure during Thrombectomy by Endovascular Route for acute ischaemic STROKE (MASTERSTROKE Trial)		
Short title	MASTERSTROKE		
Locality:	**ADHB 7773**	Ethics committee ref:	**18/NTB/55**
Lead investigator:	**Dr Douglas Campbell**	Contact phone number:	**3757095**

Thank you for taking the time to talk to us about the Masterstroke Study. We appreciate that right now everything may be overwhelming and there is a lot of information to take in. The following information tells you about the study and what is involved. You can read through this at your own speed so that you can have an idea of what is happening. Please ask as many questions as you need to so that you understand what is happening and make notes on this document to remind you to ask something that may come up later.

What the study is about and what it involves:

- The reason *(name of patient)* _____ is considered eligible to be part of the Masterstroke Study is that a clot is blocking the blood flow to their brain. This clot needs to be removed urgently; and the procedure requires a general anaesthetic. An important aspect of anaesthesia is blood pressure management . As part of our commitment to provide the best care and improve outcomes for our patients we often look at our practices; for this study we are comparing two levels of Blood Pressure management to see if there is a difference in how people recover after their stroke. We have called these two levels "standard" and "augmented". We are going to ask the anaesthetist to target a blood pressure within either of these two based on randomisation. Randomisation means they have a 50/50 chance of being allocated to receive either of the Blood Pressure levels explained below. We do not know which treatment is best for improving outcomes after a stroke, and the design of the study makes sure we are comparing the groups equally. Neither, you, the patient, or the research team have been or will be told which treatment they received.
- 'Standard' – maintain SBP at 140+/-10mmHg from the start of anaesthesia until the return of normal blood flow to the brain after removal of clot.
- 'Augmented' - maintain SBP at 170+/-10mmHg from the start of anaesthesia the return of normal blood flow to the brain after removal of clot.

To maintain the set Blood Pressure of the group that they are in, we ask the anaesthetist to be extra vigilant at staying within the level and they can do this by using their Standard treatment. We document what medications they give, including fluids and other anaesthetic drugs.

After the clot is removed, we continue to follow-up the patient for 90 days. We see them every day in hospital and call at 90 days to see how things are going. We don't ask them to do anything extra for the follow-up, the information we collect is standard of care.

Consent is an integral part of research; we would normally ask a person if they give their permission to be involved in a study. We explain the study, why we are doing it, the benefits and any risks as well as the fact that research is voluntary. We realised that patients who need to have a clot removed from their brain are not able to provide their own informed consent because of the effect it can have on how they understand information. With this in mind, we have asked the NZ Health and Disability Ethics committee to approve the **"Best Interest agreement"** for patients who need clot retrievals. This means we ask a doctor who is involved in the patients care but is not part of the study to consider whether they think it is in the best interest to be involved. We call this process an independent physician agreement.

As well as the independent physician agreement we make every attempt to talk to families so that we know how the family feels about the study. Sometimes this is not possible before we remove the clot, in this instance we document that no discussion occurred and that we discuss this with you as soon as possible.

If the doctor agrees that this is in the Best Interest, "Best Interest" agreement. This agreement and your views, when available, will be documented in the clinical notes. If you or the independent doctor or you feel that this is not the right thing to do at this time, we do not go ahead with the study and follow all the normal practices for this group of patients. Once, the patient is able to work through the information we ask their permission to continue with follow-up.

Thank you again for taking the time to talk us, we know that this can be a very stressful time.