INFORMATION SHEET

Study Title: Type 2 Diabetes Mellitus and Cognitive Decline - a study of vascular mechanisms

Chief Investigator: A/Prof. Velandai Srikanth (Dept. of Medicine, Monash University & Menzies Institute for Medical Research), A/Prof James Sharman (Menzies Institute for Medical Research).

What is the purpose of this study?

Diabetes may have effects on the blood vessels of the brain or on brain cells themselves. However, these effects are poorly understood at present. We are conducting this study on people with Type 2 Diabetes Mellitus over the age of 55 years in order to better understand the mechanisms by which diabetes may affect the brain. *In particular we are interested in the effect of ambulatory blood pressure on this relationship.* Understanding these mechanisms may help towards developing new treatments to preserve brain health in people with Diabetes Mellitus. The data collected may be used in future follow-up research if the need arose. This has received support through a major grant from the National Health and Medical Research Council.

Who is being asked to participate?

People aged 55 and above with Type 2 Diabetes Mellitus

Study procedures

There will be 2 phases of measurement, 2 years apart. After the first phase, participants will be re-contacted 2 years later and invited back to have the measurements repeated. The following protocol will be re-administered at both visits:

1. Magnetic resonance imaging (MRI) of the brain. MRI scans are safe and not associated with radiation. Very occasionally, some people may experience mild discomfort from the noise in the scanner.
2. Measure of physical activity (using accelerometers), and other physical measures such as hand strength and walking speed.
3. 24 hour blood pressure measurement. You will be provided with a portable blood pressure cuff that you wear on your left arm for 24 hours with a small monitor which is worn around the waist under clothes. You will be fitted with the cuff and provided with advice on its use before you leave. The cuff will inflate at regular intervals just like a normal BP device. You will be able to do your usual activities while wearing the cuff however the cuff should not get wet (i.e. no swimming, shower or baths).
4. Measures of height, weight, and waist circumference.

5. Measures of cognitive ability (e.g. thinking, memory and reasoning).
6. Questionnaire measures (occupation, smoking, health problems, diabetes management, medications, diet).
7. A retinal (eye) photograph to look at blood vessel health.
8. A fasting blood test to check for factors that are important for health in older people including blood glucose, cholesterol levels and kidney function. DNA will also be extracted from these blood samples to study the influence of genes associated with brain ageing on diabetes-related outcomes.
9. A test of a spot urine sample looking for protein.
10. A simple test of skin ageing in which a fluorescent light is shone for 30 seconds on the forearm. This is painless, safe and does not involve any radiation.
11. A test of walking whilst completing a cognitive task
12. A measure of blood flow in the skin with a non-invasive laser (Laser Doppler Flowmetry)

Feedback

We will provide some feedback to participants regarding their health from the information collected above. This may include health related data such as blood pressure, height, weight, blood glucose levels, either sent directly to the participant or to their medical practitioner.

Payment to subjects

Reimbursement will be offered for travel expenses in case of transport difficulties.

Possible risks or discomforts

The study involves some minor risks. Blood sampling may occasionally result in temporary discomfort and bruising. Ambulatory BP measurements occur over 24 hours and require regular cuff inflation and deflation. Although this may cause some minor discomfort, it involves much the same as routine ambulatory blood pressure recordings that are done in clinical settings.

How will blood samples be stored?

The sample may be stored for up to 15 years to potentially study future scientific questions regarding the process of brain ageing. At the end of this time the sample will be destroyed according to the appropriate local procedures for destruction at the time. Your name or any personal information that may uniquely identify you will not be associated with your sample. If the researchers wish to store (or “bank”) the samples for a longer period, you will be asked whether you agree to this and, if so, will be asked to sign a specific consent form.

How will the DNA sample be used?

The DNA sample will be used to test for the ApoE gene and some other genes related to ageing. Although some of these genes have been associated with risk of dementia, testing for them is not part of routine clinical care because they do not reliably aid in predicting who will develop Alzheimer’s disease and are mainly research tools at present.

We will only be studying whether these genes influence the effect of diabetes on the brain, to advance biological understanding, and hence only for research purposes. Because of this, genetic results obtained through this research will not be fed back to participants.

Confidentiality

All data collected in this study will be maintained on confidential password protected databases at the Menzies Institute for Medical Research and Monash Medical Centre, Melbourne. Access will be limited to the investigator team, which include support staff.

Freedom to refuse or withdraw

Participation is entirely voluntary and individuals who decide to take part in the study can withdraw at any time without any prejudice to their future care.

Contact persons

The contact persons for this study are Ms Kate Butorac, Project Manager for the study, (phone 6226 7766), or A/Prof. Velandai Srikanth, via Menzies Institute for Medical Research reception (03) 6226 7700 or Monash University (03) 9594 5581.

Concerns or complaints

This project has received ethical approval from the Tasmanian Health and Medical Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this study you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants.
You will need to quote H13965.

Or contact

Human Ethics Officer, Monash University Human Research Ethics Committee, First Floor Building 3e, Monash Research Office, Clayton Campus, Monash University, VIC 3800
Phone: (03) 9905 5490 Fax: (03) 9905 3831
Email : muhrec@monash.edu
You will need to quote Project No: CF10/0984 - 2010000502

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