The George Institute for Global Health

athena action to promote brain health in adults trial

Information before online consent and questionnaires

What is the study about?

You are invited to take part in a pilot feasibility study for a trial called ATHENA. This is because you have slightly raised blood pressure and your memory or thinking skills may not be as good as they were in the past. ATHENA is designed to test if a new type of blood pressure pill – the 'Triple Pill' – could be used over the long-term to help prevent memory problems, and perhaps even dementia. This pilot feasibility study aims to find out whether we can run ATHENA without the need for face-to-face contact.

There are three parts to the study, with entry to the next stage dependent on your eligibility. Before you can start, you must provide consent by pressing the 'I Agree' button at the bottom of this page. Once you have done this the Consent Form will be available for you to download or can be emailed/posted to you.

Part 1

The first part is an online screening questionnaire to check if you are suitable for the study. If you are, we will collect your contact details (telephone number, email address and home address) so you can continue to the second part. The questionnaire will take you around 10 minutes to complete.

Part 2

In the second part, we will talk to you over the phone to explain more about the study, go through our check list, and perform a simple test of your memory. The telephone call will take around 40 minutes. If you are eligible, we will send you a blood pressure machine (OMRON) with instructions for use. You will be required to measure your own blood pressure. It is important that you don't use this blood pressure machine on any other members of your household during your participation in the study.

You will be required to download the blood pressure measurements using an app called *OMRON connect* on to your personal smart phone The study staff will help you to set this up. This app records data from the blood pressure machine and provides an easy-to-use dashboard for viewing recent measurements and tracking progress.

Your personal data (such as your username and address) will be stored on your smart device only. The blood pressure data will be automatically sent to your personal cloud linked to your smart device account, and no data or app usage will be sent to the developer.

We will also send you blood test form to be done at your local pathology centre within a week. Collection of a blood sample (normally taken from a vein of your arm) will be performed to test your biochemistry, kidney and liver function, and electrolytes. It will involve taking approximately 10 ml of blood which is around 2 teaspoons.

Once we receive your blood pressure and blood test results, we will contact you again to explain the next steps. The results must be within a certain range for you to continue to the third part.

Part 3

In the third part, we will only include people who have slightly raised blood pressure and whose memory or thinking skills may not be as good as in the past. This is because we know that these people may be more likely to develop dementia later in life.

If you are eligible to proceed to the third part, you will be provided with a further Participant Information Sheet and Consent Form specific to taking the study drug. You will be provided a copy to read and if you agree to proceed this will be signed by yourself and the Study Doctor, you will be provided with a copy of this signed Consent Form via email or post.

We think that using a new type of blood pressure lowering drug which combines three medications at low dose into a single capsule, the 'Triple Pill', may help with your memory or thinking skills. The 'Triple Pill' is already approved for the treatment of high blood pressure but no-one has looked at whether it will help with thinking skills. The ATHENA study is the first step in this process.

Are there any risks?

All medical treatments involve some risk of injury or side-effects. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. The risks associated with the study medications are well-known and are outlined below.

Study Medication

The possible side-effects of the Triple Pill are the same as if you were to take each of the medications separately. However, it is expected that at low doses, such as those used in this study, any side-effects are unlikely to be severe and to resolve rapidly once the medication is stopped. The known side-effects most often seen when taking the full dose of the medications being used in the study are:

Common side-effects – occur in 1 to 10 of every 100 patients:

- nausea, diarrhoea, dizziness, muscle pain, low blood pressure

Uncommon side-effects – occur in 1 to 10 in every 1000 patients:

- sleepiness, pins and needle sensation in the body, insomnia, back pain, blurred vision
- low appetite, low blood sugar (symptoms of hunger, sweating, shakiness and/or weakness)
- allergies (such as skin rash, itching, hives, swelling and/or shortness of breath)

Rare and very rare side-effects – occur in less than 1 in 1000 patients:

- weight loss, fever, heart irregularities (sensation of fluttering in the chest, racing or slow heart rate, shortness of breath and/or dizziness), weakness, coughing.

Telmisartan and indapamide, two of the three BP-lowering medications, contain the additives lactose or sorbitol. People with the following rare hereditary conditions should not take this medicine:

- Galactose intolerance (inability to break down the sugar galactose)
- Lapp lactase deficiency (missing or low levels of the enzyme lactase)
- Glucose-galactose malabsorption (poor absorption of the sugars glucose and galactose)
- Fructose intolerance (inability to break down fructose, a sugar found in fruits and vegetables)

Taking telmisartan made with lactose is not likely to affect persons with lactose intolerance.

Blood Collection

The risks of a blood test include pain, a bruise at the point where the blood is taken, redness and swelling of the vein, infection and rarely fainting.

This study has received ethical approval from the Sydney Local Health District (RPAH) Human Research Ethics Committee (protocol X20-0284). This research is conducted by the George Institute for Global Health at the University of New South Wales. If you have any questions, please contact us on: ATHENA@georgeinstitute.org.au

Online consent before pressing the 'I Agree' button below

☐ Yes	☐ No	I have read the Participant Information Sheet (also available to download here)
☐ Yes	☐ No	I understand the purposes and study tasks of the research described above
☐ Yes	☐ No	I freely agree to participate in this research study and understand that I am free to withdraw at any time and this will not affect my relationship with the George Institute for Global Health or the University of New South Wales and/or the study team
☐ Yes	☐ No	I understand this study will involve the access to my medical records
☐ Yes	☐ No	I understand the study team will collect the contact information of my General Practitioner and will communicate with my general practitioner
☐ Yes	☐ No	I understand my contact details will be provided to Syntro Health and to their courier service to facilitate delivery of the study drugs.
☐ Yes	☐ No	I agree to participate

Online information after questionnaires (only for those who are ineligible)

If you need help with any memory or thinking issues, you might consider visiting your General Practitioner (GP) or other health professional. If you don't have a GP, there are some online service locators to help you find a GP or other services such as Health Direct.