Will a supplement help your diabetes?

Are you interested in trying a supplement that might help your Type II diabetes?

Join our MitoQ Study to find out if one month of treatment can improve the way your arteries react.

WE ARE LOOKING FOR VOLUNTEERS

between 45-75 years old, who have Type II diabetes and have a heart condition.

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Approved by the University of Human Participants Ethics Committee on 19 Dec 2016 for three years. Reference number 018481

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Participant Information Sheet

MitoQ: A pilot study into the effects of MitoQ on endothelial dysfunction in participants with type II diabetes and coronary vascular disease

Researcher: Caroline Alsweiler, Email: csor001@aucklanduni.ac.nz

Principal Investigator Dr Andrea Braakhuis, Email a.braakhuis@auckland.ac.nz

Co-Investigator: Dr Clare Wall, Email c.wall@auckland.ac.nz

Introduction of the Researchers

I am a student currently studying towards a Masters in Health Science at the University of Auckland. I also work for Green Lane Coordinating Centre as a Clinical Trials Manager and project manage cardiovascular clinical trials in New Zealand and other countries. For my masters qualification I am working on a project with two academic staff members: Drs Clare Wall and Andrea Braakhuis both from the University of Auckland.

About this Project

You are being invited to take part in a clinical research study. The study is designed to see if a common technique used to look into the way your arteries behave will improve if you take a specific nutritional product. The study includes people like you who have Type II Diabetes and have a known cardiac condition for which you are taking medications to manage. If this study is successful, a second study which will be similar but with a bigger group of people will be conducted. That is why the study is called a pilot study.

The aim is to see if the study design works and to see if the nutritional product can change the way the artery reacts after a month of taking the product that is being used in the study.

I expect that the results from the study will show that the measurement before and after taking the nutritional product shows a difference between the group that took the product and the group that took the dummy product (called a placebo).

You are being invited because you have Type II diabetes and a cardiac condition and are between 45 and 75 years of age.

What is the number of study participants and what is the duration of my participation?

I am looking to include up to 20 participants in the study. The expected duration of involvement in the study will be for 1 month. There are two study visits; one at the beginning which will last about 1 hour and one at the end which will be shorter, estimated to take 45 minutes. I would like to call/text or email you 2 weeks after you have started taking the nutritional product to see how you are going and to see if you have any questions. This would be a 10 minute phone call.

What are the study treatments?

The study treatments are MitoQ which is a nutritional product or placebo. MitoQ is s an antioxidant designed to accumulate within your cells in order to protect against oxidative damage that can occur. MitoQ is available in pharmacies in New Zealand and you do not need a prescription to purchase this product. For the study, you will be randomized (allocated by chance, not by the researcher´s decision) to one of two groups. If you are allocated to the MitoQ group, you will receive four 5mg capsules to take each day for 1 month. If you are allocated to the placebo group, you will receive four dummy capsules to take each day for 1 month. The placebo capsules are made exactly the same as the MitoQ capsules but they don't have MitoQ in them. It is best to take the capsules at the same time each day with water before a meal.

What are the study procedures?

You will be asked to attend the clinic at the Maurice & Agnes Paykel Clinical Research Unit, Liggin's Institute, 85 Park Road, Auckland, a map with directions will be provided to you with this information sheet. At the clinic visit you will be asked to have your height, weight and heart rate measured then have a blood sample taken. The amount of blood collected will be approximately two tablespoons. I will ask about your current medications that you take daily. The other procedure will be an ultrasound performed on the artery in your upper arm. The technique used in the study requires a blood pressure cuff to be inflated for 5 minutes before the measurement is taken. Then the cuff is released and the ultrasound measurement is made. The process will take approximately 15 minutes. The ultrasound is a test that uses high frequency sound waves to generate pictures of your artery. During the test, you generally lie on your back; gel is applied to your skin to increase the conductivity of the ultrasound waves. The researcher will then move the small, plastic transducer over your arm. The test is painless. The machine then analyses the information and develops images of your artery. These images are seen on a monitor. The researcher will use the images to take measurements of your artery. After the study I will contact your G.P. to request a recent HbA1c result they have for you to compare them to the result at the beginning of the study.

Should you wish to continue with MitoQ you will be given the option of taking open-label MitoQ (i.e. there will be no placebo) for 3 months' following the end of the 1st month. Then a blood sample to test your HbA1c will be collected. This is an optional extension and you can choose to take part or not and this will not affect your participation in the 1 month study period. If your GP has recently taken an HbA1c sample at the end of the 3 months, you can provide this result so that another blood sample is not taken by me.

What are the possible benefits to participate in this study?

By the end of the study we will have the answer about if this is a good study design and if the nutritional product MitoQ improves the behavior of the artery. By taking part in this study you will possibly help to further knowledge in nutritional products that may help people like you

What are the possible risks to participate in this study?

The risks associated with the blood sample collection include pain, swelling, or bruising, fainting, and infection. During the ultrasound procedure, you could have a reaction to the gel, although this is rare. The sound wave frequency used during the procedure is safe and does not cause any damage to your tissues. There are some possible effects that some people have reported while taking the nutritional product. Some people get sore stomachs which may include a feeling

of nausea. If this happens to you, you should stop taking the study treatment and call or email the researcher.

Funding

The funding for this research has been provided through a Callaghan Innovation and Antipodean Pharmaceutical research grant. They have provided the funds to run the project but have not been involved in the study design and will not participate in any way. Antipodean Pharmaceuticals have also provided the MitoQ and matching placebo for the study. The final study data will be provided to Antipodean Pharmaceuticals but this will not identify you as you will be assigned a study ID which is unique and used for all study reports….

Voluntary Participation and Compensation:

Being in this study is voluntary and you can choose to participate/ not participate or withdraw from the study at any time without providing a reason. You will be provided with a map when you receive this information sheet to give you instructions for parking and finding the clinic rooms where the study visits will be conducted. You will not need to pay for parking during the visit. You will be provided with a $10 petrol voucher for each visit you attend. While you are participating in this research project, you should not concurrently participate in another research project for your safety.

Will I be covered should anything happen to me related to the study?

If you have an illness or event while on the study you should seek medical help through your local doctor or in case of an emergency, go to your local hospital emergency department. If you were injured in this study, which is unlikely, you would potentially be eligible to apply for compensation from the University of Auckland.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

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Data Storage, Retention, Destruction and Future Use?

All study data created during the study will identify you by a unique study ID. The study documents will be managed and handled in accordance with standard research procedures which ensures they are protected and secure at all times. There will be a master participant list that is held securely in the Faculty of Medical and Health Science which will link the unique study ID to your name. This master participant list will be kept separately to all other research documents which collect information about you. You are able to request that the data you have provided be withdrawn until 1 Jun 2017, when data analysis will begin. To withdraw your data, please contact one of the researchers listed at the end of this form and request that the data you have provided be withdrawn from the study.

The written data collected will be stored on University of Auckland property in a locked filing cabinet, and all computerised data will be stored on the University of Auckland computer system which is protected by password access. After six years, the written data will be destroyed by shredding and the computer files will be erased.

Will my participation be kept confidential?

All the information you provide is confidential, and will be available to the researchers involved in this project and the funders only using your unique study ID.

Because of the study design, your anonymity cannot be guaranteed. However the data you provide will be coded and your identity will be kept in confidence to the researchers.

All data provided will be analysed in aggregate form, and may subsequently be used to prepare peer-reviewed journal articles and in conference posters and presentations. No data that could identify any individual participant will be reported.
You do not have to take part in this research if you do not want to. You can also stop participating in the research at any time and your data will not be included in the analyses.

Will I receive the results from the study?

Once the research has been completed and the data has been analysed, you will be sent an email containing results of the research if you have indicated on the Consent Form that you would like to receive this. Should you wish to discuss the research further, a telephone call or face-to-face meeting can be arranged with the one of the study investigators.

Your General Practitioner may be contacted to confirm details about your medical history or to provide additional information if required, only if you agree to this contact.

Contact in case of questions

Student Researcher Name: Caroline Alsweiler, Email: csor001@aucklanduni.ac.nz

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For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: ro-ethics@auckland.ac.nz.

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 16 Dec 2016 for 3 years, Reference Number 018481.