



CENTRAL NORTHERN ADELAIDE HEALTH SERVICE
The Queen Elizabeth Hospital & Lyell McEwin Hospital

PATIENT INFORMATION SHEET

Title: POLYCYSTIC OVARY SYNDROME AND CARDIOVASCULAR RISK : PLATELET AND ENDOTHELIAL FUNCTION – EFFECTS OF AGE

Protocol Number:2006085

INVITATION TO PARTICIPATE

We invite you to participate in a research project which will help us better understand the association between polycystic ovary syndrome (PCOS) and cardiovascular disease. We hope that the findings of this study will help us better manage this condition in future.

However, before you decide whether or not you wish to participate, we need to be sure that you understand

**why we are doing it, and
what it would involve if you agreed.**

We are therefore providing you with the following information.

Please read it carefully and be sure to ask any questions you have.

The Doctor conducting the research will be happy to discuss it with you and answer any questions that you may have.

You are also free to discuss it with outsiders if you wish (ie family, friends and / or your local Doctor).

You do not have to make an immediate decision.

Your participation is purely voluntary.

Should you agree to enter the trial, you may change your mind and withdraw at any stage.

PARTICIPATION IS VOLUNTARY

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without providing a reason.

Your decision to take part, not to take part or to withdraw will not affect your routine treatment, your relationship with those treating you, or your relationship with The Queen Elizabeth Hospital.

BACKGROUND TO THE STUDY

Our pilot study has shown that young women with PCOS, regardless of their weight, show abnormalities in their platelet (small component of the blood responsible for clotting) and arterial stiffness. The aim of this research study is therefore to evaluate if these abnormalities are affected by age.

The study will compare platelet and arterial function of patients with PCOS with that of age- and weight- matched controls.

We will be inviting a total of 80 patients with PCOS and 80 patients without PCOS (controls) over the age range of 20-60 years to participate in this study.

This research study is funded by The Queen Elizabeth Hospital.

PROCEDURES AND TREATMENT

The study will take place at The Queen Elizabeth Hospital on a single day, for approximately 2 hours. Before the study can begin you will need to be assessed to see if you are eligible for entry into the study. You will be excluded from this study if you are on aspirin/clopidogrel (blood thinning) therapy, pregnant or on fertility treatment. You will then be asked to sign a consent form if you decide to be a participant in the study.

Study day: Fifteen minutes before the study commences you will be asked to rest in a lying down position. You will remain in this position for the duration of the study (\approx 45 minutes).

During the study the following will be performed:

- 1) A resting ECG (heart tracing) which will be obtained by placing sticky dots across your chest/body.
- 2) A blood sample (total volume 60mls) which will be withdrawn from a vein for the analysis of platelet function and endogenous (within the body) levels of substances which modulate platelet function. Platelets are small cells within the blood stream that are responsible for clotting.
- 3) Applanation tonometry : This is a way of measuring the stiffness of your arteries using a pressure-measuring device placed on your wrist. You will then be given 2 drugs (listed below), which are used to increase the size of your arteries through different mechanisms and therefore provide means to test the responsiveness of your arteries.

MEDICINES AND DRUGS

You will be given 2 drugs, which are :

- 1) a small dose of a drug (25 mcg) called glyceryl trinitrate (a low dose compared to that used in patients with angina/heart disease), given sublingually (under the tongue)
- 2) and subsequently two puffs (400 mcg – normal doses) of an inhaled drug called salbutamol, also known as ventolin (used in asthma treatment)

PATIENT MANAGEMENT

The study will be stopped immediately should you develop any discomfort or pain, and appropriate medical treatment will be given.

DISCOMFORTS, RISKS AND SIDE EFFECTS

The blood sample will be taken via intravenous access (a small tube placed in your arm): this causes mild discomfort and may lead to local bruising.

The possible side effects of glyceryl trinitrate include headache, dizziness, flushing, fast heart rate, low blood pressure and fainting. However, the effects are very short-lived.

The possible side effects of salbutamol include tremor and fast heart rate. Again, the effects, rapidly dissipate with time.

The study will conclude only when your blood pressure has returned to normal.

You will be supervised at all times during the study.

PREGNANCY

Patients will be excluded if they are pregnant.

WHAT WILL HAPPEN TO THE INFORMATION COLLECTED?

Your participation in this study will be treated as confidential. Any records or results relating to the study shall not be disclosed to any third party other than representatives of The Ethics of Human Research Committee at the Central Northern Adelaide Health Service, or regulatory bodies for medicines, or as may otherwise be required by law. The data will be held locally for the duration of the study. Your identity will remain confidential. The Central Northern Adelaide Health Service Cardiology Unit will ensure that they comply with any national drug protection regulation.

WHAT ARE MY RIGHTS?

If you become injured during this study, and your injury is a direct result of the effects of study procedures, The Queen Elizabeth Hospital will provide reasonable medical treatment. Your participation in this study shall not affect any other right to compensation you may have under common law.

To obtain more information, please feel free to contact us (details provided below)

IS THERE ANY PAYMENT FOR PARTICIPATION?

There will be no payment for your participation in the study. There is no anticipated cost to you other than your time.

If you sustain a bodily injury that is caused by the study procedure, you will be reimbursed for reasonable physicians' fees and medical expenses necessary for treatment of the injury not covered by medical and hospital insurance.

BENEFITS OF THE RESEARCH

Participating in the study will not benefit you directly. However, it will give further understanding of PCOS and its association with heart disease which will increase medical knowledge and health outcomes for individuals with PCOS.

WHAT IF I HAVE A QUESTION ABOUT THE STUDY?

You have the right to ask any questions concerning the potential and/or known hazards of this study at any time. You will be informed of any significant new information pertaining to your safety. If you have any questions concerning the study please contact:

Principal Investigator
Prof John Horowitz
Cardiology Unit
The Queen Elizabeth Hospital
Tel: 82226000 pager 20650 (at all times)

Or

Co-Investigator
Dr Wai Ping Chan
Cardiology Unit
The Queen Elizabeth Hospital
Tel: 82226000 pager 47855

The Central Northern Adelaide Health Service Ethics of Human Research Committee (TQEH & LMH) has approved this study.

Should you wish to speak to a person not directly involved in the study in relation to

- matters concerning policies,
- information about the conduct of the study
- your rights as a participant, or

should you wish to make a confidential complaint, you may contact The Executive Officer of this Committee, on (08) 8222 6841



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CONSENT FORM

Title: POLYCYSTIC OVARY SYNDROME AND CARDIOVASCULAR RISK : PLATELET AND ENDOTHELIAL FUNCTION – EFFECTS OF AGE

Protocol Number:-----

I, the undersigned

hereby consent to my involvement in the research project explained above.

- I have read the information sheet, and I understand the reasons for this study. The research worker has explained the ways in which it will affect me. My questions have been answered to my satisfaction. My consent is given voluntarily.
- I understand that the purpose of this research project is to improve the quality of medical care, but my involvement may not be of benefit to me.
- The details of the research project have been explained to me, including:
 - The expected time it will take
 - The nature of any procedures being performed, and the number of times they will be performed
 - The nature of any medications I may be given
 - Any discomfort which I may experience
- I have been given the opportunity to have a member of family or a friend present while the project was explained to me.
- My identity will be kept confidential, and nothing will be published which could possibly reveal my identity.
- My involvement in the study will not affect my relationship with my medical advisers. I understand that I am able to withdraw from the study at any stage without having to give a reason, and that by withdrawing it will not affect my treatment at this hospital in the future.

PATIENT SIGNATURE **DATE**/...../.....

WITNESS: **DATE**/...../.....

INVESTIGATOR **DATE**/...../.....

Patient Information Sheet and Consent

Title: Polycystic Ovary Syndrome and Cardiovascular Risk : Platelet and Endothelial Function - Age

Version...1.. dated...01/09/06.....