Establishing a screening test for complement activation in patient blood samples

PARTICIPANT INFORMATION SHEET

PROJECT DETAILS

Title:	Establishing a screening test for complement activation in patient blood samples
HREC Reference Number:	2022/ETH01468
RGO Reference Number:	2022/STE02551
Principal Investigator	Dr Ritam Prasad
Location:	Calvary Mater Newcastle

Introduction

You are invited to take part in a research study. This study is **establishing a screening test for complement activation in patient blood samples**. The objective is to confirm if a new laboratory test can identify increased complement activity in patients with certain medical conditions. These conditions are:

- atypical haemolytic uremic syndrome (aHUS)
- anti-phospholipid antibody syndrome with thrombosis (APS)
- catastrophic Antiphospholipid antibody syndrome (CAPS),
- HELLP syndrome.

Complement is a family of proteins that form part of our immune system. They are responsible for fighting invading microorganisms. Usually the complement system turns on when the body senses invading microorganisms.

Sometimes it can turn on in patients with certain medical conditions even when there is no invading microorganisms. This is known as increased complement activity. Right now there are no simple tests to identify increased complement activity in a blood sample.

The aim of this study is to establish that a new test we have developed can detect increased complement activity. The test will help in early identification and treatment of some of the conditions mentioned above.

What is the research about?

The research involves collecting and testing blood samples. This will be from participants with the conditions listed above, and healthy volunteers with no known diagnosis of these conditions. . Samples will be transported to a research lab based at Calvary Mater

Newcastle Hospital. The research team at the hospital will then perform the study test on the samples.

If the new test works, these results would be published in medical journals and one day may be offered routinely.

Where is the research being done?

The study is being conducted by investigators at Calvary Mater Newcastle. The study samples will be processed at Calvary Mater Newcastle.

The study is being supported by a Science & Education Research Grant from the Thrombosis and Haemostasis Society of Australia and New Zealand.

The Coordinating Principal Investigator for this study is Dr Ritam Prasad.
The Principal Investigator at Calvary Mater Newcastle is Dr Ritam Prasad.

Who can participate in the research?

We are seeking participants aged over 18 years to participate in this study. You are being invited to participate in this study as you are a healthy volunteer, or your treating doctor has diagnosed you with one of the following medical conditions. These conditions have been selected for this study from a wide range of health issues to help confirm:

- an increase in complement activity (positive cohort), and
- no increase to complement activity (negative or control cohort).

As a participant, you will be part of one of these groups:

1. atypical haemolytic uremic syndrome,
2. anti-phospholipid antibody syndrome with and without thrombosis,
3. catastrophic antiphospholipid antibody syndrome,
4. current or previous diagnosis of HELLP syndrome,
5. unprovoked deep venous thrombosis,
6. cold agglutinin disease,
7. acute kidney injury or chronic kidney disease,
8. low risk pregnancy in the third trimester with no history of HELLP, or
9. healthy volunteers

What choice do you have?

Participating in this study is entirely voluntary. You do not have to take part in it. No matter what you decide, it will not affect your medical care. There will be no impact on your relationship with the staff caring for you. Only your treating doctor and the staff in this study will be aware of your choice to participate or not.

What would you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to read the Participant Information Sheet. You will also sign the Consent Form. You will be given a copy of the signed form to keep for your records.

You will be asked to provide a single blood sample. This will be at a participating pathology collection site, during your routine hospital visit or at your maternity clinic. During this collection you will be asked to provide a 16mL (approx. 3 teaspoons) from a vein in your arm. This can happen at the same time as a routine blood collection you require for your condition.

The study researchers would also like access to your medical record for information relevant to your diagnosis and this study. The following information about you will be collected:

1. Your age at time of consent
2. Your gender
3. Your diagnosis and some clinical information relevant to your condition e.g. past or current medications to treat the condition
4. Your most recent blood test results

The data from your sample will be analysed as part of the study. Your blood sample will only be used with this new test and stored as a frozen sample. This frozen sample may be used for future studies with your consent. All information in this study will be stored at the hospital on password protected computer. Any paper records will be filed in locked offices. Once the study has finished, records will be retained in a locked storage facility for 15 years. They will then be disposed of appropriately.

It is possible that in the future, new testing procedures or studies may be developed in relation to these conditions. We would like to continue to securely store your sample for future research carried out at Calvary Mater Newcastle. This would only be with your consent. Your consent form includes a yes or no option in relation to keeping your sample for future research. Any future studies would require the approval of the Hunter New England Research Ethics Committee before your sample is used.

Project samples that are not for future research will be safely destroyed after all study analysis is complete.

What are the risks and benefits of participating?

Risks

The only risk with this study is venepuncture. This is the inserting the blood collection needle into a vein in your arm. If you are part of one of the diagnosis groups, this procedure has been performed in the diagnosis and management of your condition.

The taking of blood, by injecting a needle into a vein, is a safe procedure. It is unlikely to cause any problems. Sometimes this procedure may cause pain, swelling, bruising or infection at the site. Feeling dizzy or fainting can also occur.

Benefits

You will not receive any benefits from this study. Your results from this study will not be disclosed to you.

You will not benefit financially from participating in this study. If any knowledge from this research leads to discoveries with commercial value, there will be no financial benefit to you or your family.

Will the study cost you anything?

Participation in this study will not cost you anything and you will not be paid.

How will your privacy be protected?

All samples and medical information stored by the research team in this study will only have your unique study number. The Principal Investigator at your site will have a code linking your study data to your personal details. No research staff will have access to your name, age or other personal details. Some of your health information may be sought from other health service providers e.g. your previous blood tests. If you decide that you do not want to provide this information, it may not be possible for you to join this trial.

The study results may be presented at a conference or in a scientific paper. To protect your privacy, no information will be shared that could identify you as a participant in this study. Your information is de-identified and individuals will not be identifiable in materials available to the public.

Your personal information will be accessed, used and stored in line with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If you decide to withdraw from the study, we will delete your data from our database. If the analysis of the database has already occurred, your data will have already contributed to our findings. However, we will still remove your stored data from the database so that it will not be used for any future studies.

If you wish to withdraw from the study, you can contact your doctor or complete the Withdrawal of Consent form.

Further Information

When you have read this document, Dr Ritam Prasad will answer any questions you may have. If you would like to know more at any stage, please feel free to contact the following people:

Clinical contact person

Site	Calvary Mater Newcastle

Name	Dr Ritam Prasad

Position	Principal Investigator
Telephone	02 4014 3021

Ethics

This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2022/ETH01468.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC	HNE Human Research Ethics Committee
Position	Manager, Research Ethics
Telephone	(02) 492 14140
Email	HNELHD-ResearchOffice@health.nsw.gov.au
Ref No:	2022/ETH01468

Governance

The conduct of this study at this site has been **authorised** by Calvary Health Care (Newcastle) Limited, trading as Calvary Mater Newcastle. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer listed below.

Complaints

If you have any concerns about the research conducted at Calvary Mater Newcastle, you may contact:

Name	Melissa Gavenlock
Position	Research Governance Officer
Telephone	(02) 401 64268
Email	Melissa.Gavenlock@calvarymater.org.au
Ref No:	2022/STE02551

This information statement is for you to keep.

CONSENT FORM

Name of Project: Establishing a screening test for complement activation in patient blood samples

Name of Investigator: Dr Ritam Prasad

Declaration by Participant

I have been given a Participant Information Sheet which has explained the nature, purpose, duration and likely effects of the project and what I will be expected to do.

I understand that my study doctor and the research staff involved in this project will have access to my medical records from all hospitals that I have attended as an outpatient/inpatient, for data collection and documentation during this project.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand that I may withdraw from the project at any time and I do not have to give a reason for withdrawing and this will not affect my further treatment.

❑ Yes I agree to my samples being stored for future research on my disease
❑ No I do not agree to my samples being stored for future research on my disease

First Name: _____ Last Name: _____

(Please print) *(Please print)*

Signature: _____ Date: _____

Declaration by Investigator / Researcher Member

I have discussed this clinical project with the participant and/or his or her authorised representative. I believe that I have fully informed the participant of the voluntary nature of this project and its possible benefits and risks, and I believe the participant understood this explanation.

Name: _____

(Please print)

Signature: _____ Date: _____

WITHDRAWAL OF CONSENT FORM

Name of Project: Establishing a screening test for complement activation in patient blood samples

Name of Investigator: Dr Ritam Prasad

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Calvary Mater Newcastle.

First Name: _____ Last Name: _____

(Please print) *(Please print)*

Signature: _____ Date: _____

In the event that the participant's decision to withdraw is communicated verbally, the Investigator / Research Member will need to provide a description of the circumstances below.

Declaration by Investigator / Researcher Member

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name: _____

(Please print)

Signature: _____ Date: _____