PARTICIPANT INFORMATION SHEET

Project Title: Diagnosing Inflammation in Dry Eye Disease

Researcher(s): Prof. Jennifer P. Craig, Ms Catherine Shon, Mr Isaac Samuels, Dr Alex Muntz

Researcher Introduction and Project Background:

Thank you for taking the time to read this information sheet. This information sheet covers many study details so please feel free to contact us if you have any further questions. You are welcome to share and discuss this information sheet with friends and/or whānau, before deciding to participate in this study.

I am Catherine Shon, an NZ registered therapeutic optometrist pursuing a Masters of Health Science under the supervision of Professor Jennifer Craig, an NZ registered therapeutic optometrist. This study is conducted in the Ocular Surface Laboratory at the Grafton site at the University of Auckland, where I may be assisted by 5th year MBChB student, Isaac Samuels.

Dry eye disease is a common eye disorder. Patients typically experience gritty, irritated, sometimes watery eyes and poor vision. The complex disease mechanism may involve inflammation, however, there is no agreed method for measuring inflammation in a clinical setting. If clinicians could assess inflammation more easily and consistently, treatment and management decisions may be better guided to improve patient outcomes.

In this study, we are evaluating different ways of diagnosing inflammation in dry eye disease. We will be using standard non-invasive clinical imaging devices [Keratograph 5M (Oculus), Tearcheck (E-Swin)], and a common in-office point of care test [Inflammadry (Quidel)] and comparing these methods to laboratory analysis of inflammation. We hope that at the conclusion of this research we will be able to recommend an optimal technique for diagnosing inflammation in dry eye disease to clinicians so that patients can be offered the most appropriate treatment.

Study Description:

In the first instance, contact will be made over phone or email where you will be asked questions to determine your eligibility for the study. If eligible, we will schedule a single study visit (lasting up to 1 hour) at the Grafton Eye Clinic, to undergo clinical assessment, at your convenience.
Our team is committed to establishing strong partnerships which support Te Tiriti o Waitangi and an increase in positive health outcomes for all New Zealand. Eye health services are an area of health that requires greater access for Māori, and in addressing this, the current project is incorporating and applying methods of engagement to increase participation from communities which have historically been underrepresented. Collaboration and consultation with individuals and organisations to support Māori health outcomes in this area of research are consistent feature within our work.

**Project Procedures:**
Various features of the eye’s surface will be observed using standard clinical techniques that are performed routinely for assessing dry eye. The test procedures are largely non-contact imaging techniques and pose minimal risk of harm. The procedures include:

1. Grading of ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using 3 brief, validated, dry eye questionnaires (taking a total of 5 – 10 minutes to complete).
2. Examination of the tear film and the eye’s surface with non-contact imaging devices.
3. Examination of the anterior eye, including the eyelids, eyelashes and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms.
4. Evaluation of the eye’s surface with standard clinical dyes. There is no stinging sensation when the dyes are applied.
5. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes but doesn’t touch the ocular surface.
6. Clinical evaluation of tear film biomarkers using Inflammadry - an in-office test that detects MMP-9, an inflammatory marker that is consistently elevated in the tears of patients with dry eye. There is no discomfort associated with applying this test.
7. Tear sample collection using the flush method. This involves instillation of a small volume of saline into the eye like an eye drop. We will then collect a small sample of your tears from the outer corner of your eye using a sterile microcapillary tube.
8. Impression cytology for subsequent laboratory analysis of inflammatory markers. This requires use of topical anaesthetic eye drops (standard in clinical practice). These might sting slightly (for 2-3 seconds), but soon after, the surface of your eye will feel numb. A small filter paper disc will then be touched against the conjunctiva which is the clear tissue overlying the white of your eye. This takes less than 1 second and, because of the anaesthetic, causes no discomfort.

**Possible Benefits:**
In taking part in this study, you will receive a thorough ocular surface review free of charge and can be provided with feedback about your ocular surface condition. Your contribution will help us determine the most appropriate method of diagnosing inflammation in dry eye disease. You will receive a koha of $20 MTA voucher (for petrol and/or groceries) for your time.

**How the Data will be Used:**
This study has been initiated and designed by the researchers at the University of Auckland. It is anticipated that the results of this study will be written up as a Masters project and submitted for publication in the scientific literature. You will not be individually identifiable in any report from the study. This project will only involve sample collections of tear samples and loose conjunctival cell collection by impression cytology. The samples collected for this project will be very small and are used in their entirety in laboratory analysis. No tissue samples will be used in future research. If you withdraw your consent before laboratory analysis, your collected samples will be disposed of in the appropriate manner or returned to you, or your whānau, on request.

Approved by the Auckland Health Research Ethics Committee on 27 July 2021 for three years.
Reference number AH22183.
Participation:
Participation in this study is voluntary which means you are under no obligation to take part. Neither your refusal nor agreement to take part will affect the clinical care you receive, from the researchers or any other clinicians, today or in the future. If you are a patient of the Eye Clinic, you may contact the Clinic Director should you feel that this assurance has not been met. Similarly, if you are a student at the University of Auckland, your decision to participate or not participate will not influence your academic progress in any way, and nor will it impact on your employment status as a staff member. As a student or staff member, you may contact your HoD should you feel that this assurance has not been met.

Eligibility:
There are a number of reasons you might not be suitable for this project. These include:

- If you are not willing or able to stop your current eye drops, contact lens wear or warm compresses for at least 24 hours before you attend the study visit.
- History of ocular surgery in either eye in the 3 months prior to baseline measurements
- The history or presence of any ocular disorder or condition in either eye that would likely interfere with the interpretation of the study results.
- Non-normal lid architecture affecting lid closure/blink
- Current use of punctal plugs

Incidental Findings:
Any abnormalities noted incidentally during the examination of your eye will be discussed with you and you will be offered advice about management and/or referral consistent with normal clinical care by registered health practitioners. If you do not wish to be advised of incidental findings, you will not be eligible to take part. We will ask if you would like us to contact any of the health professionals who provide you with health care. If you would like us to do so, we will ask for their contact details and request your permission to contact them on your behalf to let them know about your participation in the trial.

Data Storage/Retention/Destruction:
Clinical data (paper copies) and consent forms will be stored in a secure cabinet at the University of Auckland for six years before being securely destroyed. Electronic data will be de-identified immediately following collection and stored indefinitely on the University of Auckland Research drive. All tissue samples in the form of tears and conjunctival cells will be stored immediately after collection in a locked -80°C freezer with a de-identified label, in the Department of Ophthalmology, University of Auckland. All tissue is used up during the laboratory analysis.

Right to Withdraw from Participation:
If you change your mind about participating, you have the right to withdraw from the study at any time, without providing a reason. You are also at liberty to withdraw any data traceable to you, up to two weeks after your clinic appointment.

Confidentiality:
All participants will be assigned a unique alpha-numeric identification code to protect confidentiality. A document linking the code with your name will be stored independently of the clinical data and will be available only to the researchers. All clinical data will be collected, recorded, stored and analysed under your unique code. The linking document will be destroyed after the duration of the study. If the results of this study are to be published in the scientific literature or presented at a conference, as with the study report, you will not be individually identifiable.

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Risk of Harm:
The risk of harm during the clinical assessments is minimal, and is the same level of risk you would be exposed to during a routine eye examination involving your ocular surface. The investigators are trained to carry out these procedures safely. You will be given detailed instructions during the test procedures to minimise risks as far as possible. The investigators are trained to anticipate patient movements, however, in the unlikely event you move suddenly or unexpectedly during the test procedure, there is a small risk that contact could be made with your eye surface, and an abrasion could occur. This would usually take several hours to fully resolve, during which time your eye could be slightly uncomfortable. The abrasion would be treated, and you would be followed up according to standard clinic protocols.

Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator. You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

Contact Details and Approval:
For any queries or concerns about this study please contact one of the following researchers:

Professor Jennifer P. Craig (Principal Investigator)
Email: jp.craig@auckland.ac.nz
Telephone: 09 923 8173

Ms Catherine Shon (Student Researcher)  
Email: jsho341@aucklanduni.ac.nz

Mr Isaac Samuels (Student Researcher)  
Email: isam153@aucklanduni.ac.nz

Mobile: 022 EYE PAIN

Professor Charles N. J. McGhee (Head of Department of Ophthalmology)
Email: c.mcghee@auckland.ac.nz
Telephone: 09 923 6712

If you require Māori cultural support, you are encouraged to talk to your whānau in the first instance. Alternatively, you may contact Iwi United Engaged consultant Dr Kevin Roos by emailing kev@iue.net.nz. Another point of contact is the administrator for He Kamaka Waiora (Māori Health Team), their contact number is 09 486 8324 ext 2324. If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

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