PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Evaluation of ocular microstructural changes due to ultraviolet radiation

QUT Ethics Approval Number 8269

Research team contacts

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Why is the study being conducted?

This project is being undertaken as part of PhD research of Ishwarya Suresh Kumar.

The purpose of this project is to improve the understanding of ultraviolet (UV) associated changes in the cells on the eyelids and the front surface of the eye. In this study we will use imaging techniques to observe the cellular level changes on the eyes and eyelids due to UV exposure and a very small sample of tears will be collected to understand the difference in tear protein levels between people with and without UV eye damage.

Who are we looking for?

We are inviting you to participate if you are aged 18-70 years and are in either of these two categories.

1. Healthy people with normal ocular surfaces.
2. Individuals with UV ocular disease characterized by pterygium (a thickened, yellowish raised spot growing from the white surface of the eye), or those who have undergone surgical removal of lesions on the eyelids within the past 2-12 months.

You will not be able to participate if you have a history of refractive surgery, other ocular diseases, current contact lens user (hard or soft lenses) or used contact lens within the past 3 months, systemic illnesses such as diabetes, neurological disorders, or autoimmune diseases. If you're in group 2 and don't want to share your past history of eyelid lesion surgery, you can't participate in this study.

A screening assessment will be conducted to assess your suitability to participate in study during the initial visit after consent.

What does participation involve?

If you are suitable to be enrolled in the study, and if you belong to group 1 (people with healthy eyes), your participation will involve one initial visit (duration: ~60 minutes) in winter and a follow-up visit in summer (duration: ~60 minutes). Additionally, people with healthy eyes, will be undergoing 2 follow-up visits, each lasting 30 minutes (on same day of the baseline evaluation), to evaluate daily UV exposure across a day in winter and summer. This will help us to assess ocular surface changes due to acute UV exposure (1 day follow up) and seasonal UV change (3 months follow up). If you belong to group 2 (UV-ocular disease group), your participation will involve one visit only.

Baseline or initial visit: At the initial visit we will evaluate the health of the front surface of your eyes as normally performed during a routine eye examination. A small amount of yellow dye (sodium fluorescein) will be used to evaluate any dryness on the front of the eye. You will be asked some questions about past sun exposure and symptoms of ocular irritation. We will also examine the cells on the surface of your eyes using an imaging device called a confocal microscope. To do this we will install an eye drop (2-4 drops) to

numb the eye. We will also conduct conjunctival imaging, which is a contactless photography of the eye, to provide information on ocular surface UV damage. A small quantity of tears will be collected from your eyes using a small tube without touching the surface of the eye for tear analysis.

1 day follow up in winter and summer: Some of the people with healthy eyes will be asked to wear a UV sensor for 1 day to measure UV exposure levels in winter and summer and at the end of this day, these participants will be asked to return for re-assessment of the front of the eye, as well as the conjunctival and confocal imaging.

3 months follow up: All individuals with healthy eyes will be asked to return for a final follow up after 3 months for a repeat of all of the baseline assessments.

If you are enrolled in group 2 (UV ocular diseases group) of the study, information about the date, and type of the eyelid lesion that was removed will be sought from your treating ophthalmologist. All assessments will take place in Anterior Eye Laboratory, Q- Block, QUT Kelvin Grove campus.

What risks are involved?

Potential risk and mitigation:

a) In vivo confocal microscopy: Imaging of the ocular surface using this microscope may lead to minimal rubbing of the front surface of the eye, like that which might occur if you physically rub the eyes, for example in response to minor irritation when there is an eyelash in your eye. However, this type of rubbing heals quickly without intervention, typically within 12 hours. The part of the instrument that contacts the eye (tomocaps) is single use and disposable.
b) Anesthetic drops (numbing agent): The drops can cause transient stinging which disappears within 2 min. Use of this agent can cause very mild sensitive reactions. You will be asked if you have ever had an allergic reaction to it before; if so, you won't be able to take part in the study.
c) Fluorescein dye: There is a very remote potential to have an allergic or adverse reaction to sodium fluoresceine, but this is very low as fluorescence is a water-soluble inert stain (an agent mixed with saline that is used to assess staining of the ocular surface). You will be asked if you have ever had allergic reaction with use of this material, if so, you won't be able to take part in the study.
d) Tear collection: An unpreserved saline will be instilled without touching the eye and you will be asked to close the eyes for 5 secs and to bend towards the shoulder side, a microcapillary tube will be placed on the lower eyelid region on the temporal area and tears will be collected without touching the ocular surface using a tube. During tear collection you will only feel minimal discomfort, or it may result in mild redness and slight irritation at the corner of the eye, which should resolve a few minutes after the procedure.

Management: An examination of your eyes before and after the test will be performed to check for the ocular surface integrity. In the rare instance of damage being noted at the end of the procedures, you will be immediately discontinued from the study and a licensed optometrist or ophthalmologist who is a part of the research team will provide appropriate intervention for ocular adverse effects. Referral to an appropriately licensed and qualified individual will be provided if necessary.

All measurements will be taken using standard clinical techniques. It should be noted that if you agree to participate, you can withdraw from participation at any time during the project without comment or penalty.

If you do withdraw your consent during the research project, the researchers will not collect additional personal information from you, although the information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results, if you don't want us to use your data, please indicate us and we will not use any information collected from you.

Are there any benefits for taking part?

It is expected that this research project will not benefit you directly. However, the outcomes of the research will result in better understanding of ultraviolet associated cellular changes on the eyes and around the eyes (eyelids). During the study, the investigator will share any information regarding the measurements of your eyes that may be of interest to you.

Privacy and confidentiality

All the data and responses will be treated confidentially, and if presented or published will be anonymous. Your name or personal identity will not be used in any reports and usually the data will be presented in mean or median format. Only the research team will have access to your records and the data collected for this project will be stored securely as per QUT's Data Management Plan. Please note that non-identifiable data may be used as comparative data in future projects or stored in a secured database for secondary analysis. The tear samples left over after the completion of the analysis will be discarded to pathological disposal.

Is there any compensation?

To thank-you for your participation, the research team will provide you with gift a card (Woolworths or Coles) to the value of $20 after completing your involvement. Free parking will be organised ahead of time if required.

I am interested – what should I do next?

If you are interested in participating in this study, please contact one of the listed researchers:

Ishwarya Suresh Kumar	ishwarya.sureshkumar@hdr.qut.edu.au	3138 0214
A. Prof Katrina Schmid	k.schmid@qut.edu.au	3138 6150
Dr Katie Edwards	katie.edwards@qut.edu.au	3138 6154

You will be provided with further information to ensure that your decision and consent to participate is fully informed.

***What* if I have a concern or complaint regarding the conduct of the research project?**

QUT is committed to research integrity and the ethical conduct of research projects. If you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the QUT Research Ethics Advisory Team on 3138 5123 or email humanethics@qut.edu.au.

Thank You! ***QUT Ethics Approval Number: 8269***

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RESEARCH TEAM CONTACTS

Principal Investigator	Ms Ishwarya Suresh Kumar	3138 0214	ishwarya.sureshkumar@hdr.qut.edu.au
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STATEMENT OF CONSENT

By signing below, you are indicating that you:

- Have read and understood the information document regarding this research project.
- Have had any questions answered to your satisfaction.
- Understand that if you have any additional questions, you can contact the research team.
- Understand that you are free to withdraw without comment or penalty.
- Understand that if you have concerns about the ethical conduct of the research project you can contact the Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au**.**
- Agree to participate in the project.

☐ I provide consent to the research team to contact me for participating in future research projects

☐ I provide consent to the research team to use my non-identifiable data including demographic data for future research projects

☐ I provide consent to be included in group 1 (healthy ocular surface group)

☐ I provide consent to be included in group 2 (UV ocular condition group)

☐ I wish to receive a summary of the research outcome. To receive summary please provide with us with an email address.

Name	
Signature	
Date	

Please return the signed consent form to the researcher.