PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Diurnal variation in optical coherence tomography angiography measurements among various refractive error

QUT Ethics Approval Number 1900001156

Research team

Principal Researcher: Ms Barsha, Ph.D. student

Associate Researchers: Dr Andrew Carkeet, Principal Supervisor
Associate Professor Scott Read, Associate Supervisor
Dr David Alonso-Caneiro, Associate Supervisor
School of Optometry and Vision Science,
Faculty of Health, Queensland University of Technology (QUT)

Why is the study being conducted?

The purpose of this project is to evaluate the normal changes that occur in the blood vessels of the retina and choroid (the structures at the back of the eye over the 24 hours of the day. It will help in our understanding of the normal physiology of the blood vessels and blood flow in the eye, and the relationship between these changes and common eye conditions such as short-sightedness (myopia).

You are invited to participate in this research project because you fulfil the selection criteria of the study, of being in good general and eye health, with normal vision and exhibiting a range of normal refractive errors

What does participation involve?

Prior to enrolment in the study, we will conduct a screening examination that includes standard clinical vision and eye tests to detect any eye problems 1 week prior to the experiment and to ensure that you are eligible for the study. You will also be asked to wear an Actiwatch 2 device (a lightweight wrist-worn device that measures light exposure) for 1 week before the experiment in order to confirm the regular sleep / wake cycle and light exposure. In case if you are noted not eligible for the study after a week based upon the Actiwatch results, you will be asked to discontinue from the study.

If you are eligible for the study, your participation will involve series of measurements at seven sessions performed at the QUT optometry clinic over a 24-hour period. The measurements will be taken every 4 (± 20 minutes) hours. You will also be asked to refrain from caffeine, alcohol, tobacco and vigorous physical activity on the experiment day. Each measurement session will take approximately 30-40 minutes. The first measurement session will be conducted at approximately 9 AM, and the final session at 9 AM the following day. A total of 7 sessions (9AM, 1PM, 5PM, 9PM, 1AM, 5AM, 9AM) over a 24-hour period will be conducted.

At each measurement session, images of the retinal and choroidal blood vessels and retina, length of the eye, eye pressure, corneal thickness, blood pressure and pulse rate will be measured using

different instruments. These measurements involve looking briefly into the instrument, whilst a dim red light is shone into the eye and a light puff of air is directed towards the eye to take the measurements, or a cuff is placed around your arm.

When you are not involved with a measurement session over the study period, you will be provided with a range of different activities (e.g. computer games, watching movies) to do. You are also welcome to bring your own computer/electronic device or activity with you to use for work or entertainment during your involvement in the study. You can go out of the clinic if you wish and come back before 15 minutes prior the measurements timings during the day. You are advised to continue their normal daily activities in between measurement sessions as measurements are taken over a 24-hour period, we will also provide dinner on the day of experiment and breakfast including drinks the next day.

You will be provided with blow up mattresses in your own individual room for sleeping at the QUT optometry clinic for a comfortable overnight stay
Your participation in this research project is entirely voluntary. If you do agree to participate you can withdraw from the research project without comment or penalty. You can withdraw anytime during the study. Your decision to participate or not participate will in no way impact upon your current or future relationship with your grades at QUT.

What are the possible benefits for me if I take part?

It is expected that this research project will not benefit you directly. However, the outcomes will help to improve knowledge of the normal physiology of the blood flow in the eye throughout the day. The investigators will provide verbal feedback to you about any measurement results for your eyes which may be of interest to you or on request.

What are the possible risks for me if I take part?

There are no risks beyond normal day-to-day living associated with your participation in this research project.

Will I be compensated for my time?

No. You will not be offered any compensation. However, the research team will provide dinner on the day of experiment and breakfast including drinks the next day. The participants can indicate their dietary preferences to the researcher

What about privacy and confidentiality?

Any personal information that could potentially identify you will be removed or changed before files are shared with other researchers or results are made public. Any data collected as part of this research project will be stored securely as per QUT's Management of research data policy. Data will be stored for a minimum of 5 years and can be disclosed if it is to protect you or others from harm, if specifically required by law, or if a regulatory or monitoring body such as the ethics committee requests it. Every effort will be made to ensure that the data you provide cannot be traced back to you in reports, publications and other forms of presentation.

How do I give my consent to participate?

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

What if I have questions about the research project?

If you have any questions or require further information, please contact one of the listed researchers:

Barsha	07 31385697	barsha2@hdr.qut.edu.au
Andrew Carkeet	07 3138 5703	a.carkeet@qut.edu.au
Scott Read	07 3138 5714	sa.read@qut.edu.au
David Alonso-Caneiro	07 3138 5717	d.alonsocaneiro@qut.edu.au

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 +61 7 3138 5123 or email humanethics@qut.edu.au.

Thank you for helping with this research project.
Please keep this sheet for your information.