

PARTICIPANT INFORMATION SHEET

Title of Project: Environmental Risk Factors for Dry Eye Disease



Investigators: Prof. James S. Wolffsohn.

Dr. Leon N. Davies
María Vidal Rohr
Nikolay Boychev
Francesco Menduni

Invitation

You are being invited to take part in a research project that will be conducted at Aston University. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this

What is the purpose of the project?

Millions of people suffer from dry eye disease, causing symptoms such as redness, burning, feeling of sand or grit in the eye and light sensitivity. Dry eye disease occurs when your eyes do not produce enough tears or produce poor quality tears. This can happen for a number of reasons, including aging, hormonal changes in women and as a side effect of diseases or certain medications. Modern environments such as air conditioning, pollution and staring at digital displays can also cause dry eye symptoms. This study aims to find out how common dry eye symptoms are in the UK, the main causes and the effect on the tear film. It is part of a larger study being conducted with partners across the world.

Why have I been chosen?

You have been asked to join the study because you are 30 years of age or older and living in the UK.

What will happen to me if I decide to take part?

If you decide to join, you will be given some short questionnaires to complete, and a 30-minute tear film assessment will be performed in one eye. The tear film assessment involves looking into several instruments that will image just your eyes (you will not be identifiable from the images) in different wavelengths of light to capture your eyes redness, tear stability, oily layer thickness and volume. We will also measure the evaporation from your tears over about 10s using a swimming like goggle and analyse the saltiness of your tears with a probe which will not come in contact with the surface of your eye so is painless.

Are there any potential risks in taking part in the study?

As part of the study, moisturised strips will be used to apply some standard dyes (fluorescein 1.0% & lissamine green 1%) to your tear film. These are staining agents used to aid external examination of your eye. When applied to the eye, they may sting for a few moments. Due to their colouring (orange/yellow/green) they may cause the vision to take on a coloured appearance, but this will not last long. As soft contact lenses can absorb the dye, you are advised to refrain from wearing your lenses for at least 15 minutes. Sometimes, the eyelids and the skin around the eyes will be coloured by the stain, but this can be removed with cold water.

Do I have to take part?

It is up to you to decide whether to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

Expenses and payments

Travel expenses may be offered to you if you are not local to the University

Will my taking part in this study be kept confidential?

Yes, your participation in the study will be fully confidential. There will be no way to link any research data to any individual participant. Aston University will review the anonymised data for monitoring and analysis purposes.

What will happen to the results of the research study?

The anonymous results will be monitored and will be analysed by Aston University. The aim is to publish the results of this project. However, there will be no reference to any individual's data in any publication. Details of any publication will be conveyed to participants on request.

Who is organising and funding the research?

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 642760.

Who do I contact if something goes wrong or I need further information?

Please feel free to contact Maria Vidal Rohr by email dryeye@aston.ac.uk telephone 0121 204 4400.

Who do I contact if I wish to make a complaint about the way in which the research is conducted?

If you have any concerns about the way in which the study has been conducted, please contact the Secretary of the University Research Ethics Committee: j.g.walter@aston.ac.uk or telephone 0121 204 4665.