

Jarvis Optometrist

Participant Information Sheet

Study title: TAMS: Topical Azithromycin Meibomian gland dysfunction survey

Researcher: Mr Ian Jarvis (who has been contracted by NHS Tayside for your optometry treatment)

We are inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part. Please take time to read this information carefully. You can ask us any questions you have and talk to other people about it if you want. We will do our best to answer your questions and give you any more information you ask for. You do not have to decide straight away.

Why are we doing this study?

We are investigating the effect of the course of Azithromycin has had on your management of your dry eyes (Meibomian gland dysfunction)

What is being tested?

This is a retrospective review of your examination data that will be linked to a post-treatment survey to be completed by you

Why have I been contacted?

You were chosen from the first 40 patients that were treated with Azithromycin at Mr Ian Jarvis' practice, *Jarvis Optometrist*.

Do I have to take part?

No. It is up to you to choose, taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part you can stop the study at any time. You do not have to give a reason for not taking part. If you do not want to take part, your relationship with the medical staff looking after you will not be affected.

What will happen to me if I take part?

You will be asked to complete a questionnaire and your examination data will be collated. All data will then be used anonymously as a unique study identifier will be allocated to each participant. The results will be used for publication and help spread the knowledge about this form of treatment in the profession at large. [You will be required to complete and sign the consent form along with the](#) completed questionnaire

Will taking part in the study affect my usual care?

TAMS (Topical Azithromycin Meibomian Gland Dysfunction Survey)

PIS Version 1.1 18/09/2019 IRAS No. 269433

Jarvis Optometrist

No, we will continue to provide you with high quality care for your optical needs as before

What will happen when the study finishes?

The results will be published in a professional journal and may be presented at conferences with some anonymised quotes from the surveys

What are the possible benefits of taking part?

Your participation will help to spread knowledge about the benefits of this type of treatment

What are the possible disadvantages and risks of taking part?

There are no risks involved and all your data will be anonymised and stored securely during the study.

Who is organising and funding this research?

This study is being sponsored by NHS Tayside. It is being funded by Jarvis Optometrist. The study is being organised by Mr I Jarvis

What will happen with the information collected about me?

Identifiable information about you and the information collected about you during the study will be stored by *Jarvis Optometrist*. Only specified members of the research team will have access to this information.

Your identifiable information and coded study information will be stored securely on a password-protected database at *Jarvis Optometrist*. Specified members of the data management team will also have access to your identifiable information to manage your information and maintain the database.

Your information will be kept securely for five years after the end of the study. After five years, your identifiable information will be removed and the rest of the information will be kept for research purposes. If you would like to be informed about future studies that you might be interested to participate we will ask you to sign a consent to allow us to hold your contact details.

Jarvis Optometrist

Information which identifies you will not be published or shared.

Your study information with any information which identifies you removed may be shared with other researchers in the UK.

What if something goes wrong?

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in carrying out the trial/study or a doctor involved in your care.

If you have a complaint about your participation in the trial/study first of all you should talk to a researcher involved in the trial/study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Complaints and Feedback Team

NHS Tayside

Ninewells Hospital

Dundee DD1 9SY

Freephone: 0800 027 5507

Email: feedback.tayside@nhs.net

If you think you have come to harm due to taking part in the trial/study there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

Any significant incidental findings may trigger referral on to secondary care if consented to on the participant consent form

Insurance

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this study.

If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not expect that

TAMS (Topical Azithromycin Meibomian Gland Dysfunction Survey)

PIS Version 1.1 18/09/2019 IRAS No. 269433

Jarvis Optometrist

taking part in the trial/study will adversely affect your ability to buy insurance. Some insurers may use this information to limit the amount of cover, apply exclusions or increase the cost of insurance. Your insurer may take in to account any medical conditions you have, including any which are diagnosed as part of a research study.

Who has reviewed this study?

This study has been reviewed and approved by Health and Care Research Wales, who are responsible for reviewing research which is conducted in humans. The Research Ethics committee does not have any objections to this study going ahead.

Contact details for further information.

Chief Investigator: Ian Jarvis

Jarvis Optometrist

24-26 Arbroath Road

Dundee

DD4 6EP

Email: ianjarvis2@nhs.net

Tel: 01382-462236

Thank you for taking time to read this information and for considering taking part in this study.

If you would like more information or want to ask questions about the study please contact the study team using the contact details above.

You can contact us Monday – Friday between 09:00-17:00pm.

Jarvis Optometrist

Data Protection Privacy Notice

How will personal information be used?

We will only use your personal information to carry out this study.

NHS Tayside is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. *Jarvis Optometrist* will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To protect your rights, we will use the minimum amount of information which is personally identifiable as possible.

Jarvis Optometrist will collect information from your records for this study according to our instructions.

We will use this information to carry out the study.

Lawful reason for using your information

It is lawful for *Jarvis Optometrist* who has being contracted by NHS Tayside for optometrist treatment to use your personal data for the purposes of this study. The legal reason for using your information is that using it is necessary for the research which is carried out in the public interest.

You can find out more about how we will use your information at <http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information> and <https://www.dundee.ac.uk/information-governance/dataprotection/> and at http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk

If you wish to complain about the use of your information please email informationgovernance.tayside@nhs.net or, you may wish to contact the Information Commissioner's Office.

