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To assess the effect of antibiotic eye drops (azithromycin) on the signs and symptoms of dry eyes (Meibomian gland dysfunction)

Submission date
03/06/2023

Recruitment status
No longer recruiting

Registration date
22/06/2023

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One important factor affecting the quality of tears is the Meibomian glands' function. These are tiny glands located along the edges of the eyelids that produce an oily substance called meibum. This meibum helps to lubricate the surface of the eyes, prevent tear evaporation, and maintain the stability of the tear film. The modern lifestyle, which often involves spending time indoors with air conditioning and central heating, can have a noticeable impact on tear quality. Optometrists are well positioned to manage a condition called Meibomian gland dysfunction (MGD) within the community. In the UK, there has been an increase in Independent Prescribing Optometrists, with 500 registered with the General Optical Council. This allows practitioners to have more options for prescribing when treating MGD.

There are various treatment options available for MGD. However, patient compliance is a significant factor in determining the success of treatment, especially in chronic conditions. Research has shown that patients with long-term dry eye problems tend to have reduced compliance with lid hygiene. Finding a treatment that can break the cycle of dryness, inflammation, and keratinization of the Meibomian glands, and reduce the need for long-term management of MGD, could potentially improve the patient's quality of life and reduce the financial burden on the National Health Service, which currently supplies lubricants for ongoing treatment. The annual cost of managing dry eye disease was estimated to be around £570 per person per year in the UK.

Topical Azithromycin has been identified as a viable treatment option comparable to oral doxycycline. Research has found that it was as effective as doxycycline in restoring low levels of carotenoids typically found in MGD, thus improving tear film stability.

This study aims to analyze the effectiveness of topical azithromycin in reducing signs and symptoms of MGD, as well as the need for self-treatment methods, in a community Optometry practice in the UK.

Who can participate?
Patients with persistent Meibomian gland dysfunction (MGD) and previous treatment of lid hygiene, lubricants, heat & massage had been ineffective at relieving signs or symptoms.

What does the study involve?
The study involved patients to consent to the treatment and then to complete a post-treatment survey one year on.

What are the possible benefits and risks of participating?
Benefits, reduced symptoms and effect on lifestyle from MGD.
Risks are low, possible hypersensitivity to the drug.

Where is the study run from?
Jarvis Optometrist, a community Optometry practice (UK)

When is the study starting and how long is it expected to run for?
March 2026 to July 2020

Who is funding the study?
This study is self-funded, with research assistance from the College of Optometrists (UK)

Who is the main contact?
Ian Jarvis, ian.jarvis2@nhs.scot

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
269433

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 269433

Study information

Scientific Title
The Topical Azithromycin Meibomian Gland Dysfunction Survey (TAMS): the effect of topical azithromycin on signs and symptoms of Meibomian gland dysfunction

Acronym
TAMS

Study objectives
The use of topical azithromycin reduces signs, symptoms and self-management of Meibomian gland dysfunction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2019, Wales Ethical Approval Committee 7 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 2922 940968; Wales.REC7@wales.nhs.uk), ref: 19/WA/0253

Study design
Single centre interventional non randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Meibomian gland dysfunction

Interventions
This study was conducted in a community Optometry practice over a 2 year period (2016-2018). Patients were invited to participate in the study, who had persistent Meibomian gland dysfunction (MGD) and previous treatment of lid hygiene, lubricants, heat & massage had been ineffective at relieving signs or symptoms. The first 40 suitable patients were invited to take part in the study, to minimise selection bias.There were no general health exclusions that needed to be applied. The treatment involved taking one drop of topical azithromycin, 15mg/g (Thea pharmaceuticals) twice daily for 2 weeks and then once a day for the following two weeks. After treatment, objective data was collected from the participant record

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Topical azithromycin, 15mg/g eye drops

Primary outcome(s)
1. Meibomian gland dysfunction (MGD) measured using the Efron grading scale before and after treatment
2. Fluorescein tear break up time (FTBUT) measured after instillation of 1% Fluorescein (Bausch & Lomb minims) and measured in seconds, counted by the examiner, before and after treatment

Key secondary outcome(s))
Long-term benefit of treatment on symptoms and self-treatment methods, by post-treatment survey one year on from treatment. In brief, the survey asked the participants how their management of MGD had changed, which dry eye symptoms they had pre- and post-treatment (sensitivity to light, gritty/ burning sensation and blurred vision). They were also asked to what extent their symptoms affected their lifestyle, (reading, night driving, computer use and

watching television) and how they were affected by environmental conditions (windy, dry and air-conditioned environments). This used a combination of yes/no responses and a numerical grading of symptoms of 1-5, where 1= least affected and 5=most affected.

Completion date
27/10/2021

Eligibility

Key inclusion criteria
This study was conducted in a community Optometry practice over a 2 year period (2016-2018). Patients were invited to participate in the study, who had persistent Meibomian gland dysfunction (MGD) and previous treatment of lid hygiene, lubricants, heat & massage had been ineffective at relieving signs or symptoms.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
39 years

Upper age limit
75 years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. No Meibomian gland dysfunction
2. Managed Meibomian gland dysfunction

Date of first enrolment
02/10/2019

Date of final enrolment
13/01/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Jarvis Optometrist
24-26 Arbroath Road
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Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
University/education

Funder Name
School of Nursing and Health Sciences, University of Dundee

Alternative Name(s)
School of Nursing & Health Sciences, University of Dundee, School of Nursing & Health Sciences, School of Nursing and Health Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the study will be available on request from Ian Jarvis: ian.jarvis2@nhs.scot

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2024	12/09/2024	Yes	No
Participant information sheet	version 1.1	19/09/2019	16/06/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	12/05/2019	16/06/2023	No	No