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PARTICIPANT INFORMATION SHEET

Project Title: Can castor oil improve tear film and ocular surface quality?

Researcher(s): Prof Jennifer P. Craig, Dr Kalika Bandamwar, Catherine Shon, Carol D'Souza

Researcher Introduction:

Thank you for taking the time to read this information sheet which you have been given because you report dry eye symptoms or have received a diagnosis of dry eye or meibomian gland dysfunction. We are conducting this research project through the Ocular Surface Laboratory at the University of Auckland. The Ocular Surface Laboratory comprises a team of approximately 10 clinician scientists who undertake research with, and under the supervision of NZ registered optometrist, Professor Jennifer Craig. The research team comprises postdoctoral research fellow, Dr Kalika Bandamwar; research optometrist, Catherine Shon; and optometry student and summer student, Carol D'Souza, who are all trained clinical researchers from the Department of Ophthalmology. The focus of the Research Laboratory is to improve life for patients with 'dry eye disease'. In this particular study, we are concentrating on a form of dry eye disease that arises from a condition known as blepharitis or meibomian gland dysfunction or 'MGD'.

Project Description

Blepharitis, which includes the subcategory of meibomian gland dysfunction is a very common condition affecting up to 30% of the population. The eyelashes can develop crusts, the eyelid glands can become blocked and the oils that your tear film needs to keep the eye's surface healthy are not produced. Tiny mites (Demodex) which sometimes inhabit the eyelash follicles and glands around the eyes can worsen this condition and make affected individuals more symptomatic. Usual treatments include the use of eyelid cleansers to help break down the crusts, and artificial tears to replace the deficient tear film, but these are expensive, sometimes difficult to apply and compliance is therefore often poor. Castor oil is a natural antibacterial product, derived from the seeds of the castor bean plant (Ricinus communis). Its use dates back as far as the ancient Egyptians, who used it to treat eye irritations, and it is a component in some eyedrops today as a supplement for the tear film oil layer. The direct application of castor oil to the eyelid margins is easy and cost-effective and is reported by clinicians to offer benefits in eyelid health and reduce symptoms of blepharitis as well as supplementing the oil layer, however good quality scientific trials are lacking. We are undertaking this research project to assess whether castor oil application to eyelids improves the signs and

symptoms of ocular anterior blepharitis better than saline control, in an investigator-masked, parallel group trial.

Study design:

This study design has been chosen to minimise bias and help us to learn the true benefits of the treatment. Participation in the study will involve you applying of a tiny amount of the oil or saline control, with a rollerball applicator, to the the upper and lower eyelids of both eyes, morning and night, over the course of 1 month. We will then compare the outcomes between the treated and untreated groups. Allocation to the treated or control group is assigned according to your study number before the study starts, and the investigator who examines your eyes will be 'masked' as to which group you are in, so that this does not influence the outcomes. To keep the investigator masked, you will be asked not to share any information about which group you think you're in with the investigator when your measurements are taken at the study visits.

You will be required to attend five clinic visits in total, one visit at which the baseline measurements will be taken and your eligibility will be confirmed, and subsequent visits after 1, 2, 3 and 6 months, during which the tests will be repeated. The tests will take up to 45 minutes at each visit.

Project Procedures:

Various features of the eye's surface will be observed using standard clinical techniques that are performed routinely for assessing dry eye. These include:

1. Grading of ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using brief, validated, dry eye questionnaires (taking a total of 10 minutes to complete).

2. Examination of the anterior eye, including the eyelids, eyelashes and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms, as well as the Oculus Keratograph 5M, the Medmont E300 topographer, and the TearScience LipiView. These are used routinely in the clinical setting and do not directly touch your eye.

3. Checking for the presence of Demodex on the eyelashes using a microscope.

4. The quantity and quality of the eyelid gland contents will be assessed following gentle pressure applied to your closed lower eyelid (equivalent to that of a forceful blink).

5. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes but doesn't touch the ocular surface, may be performed.

6. Evaluation of the ocular surface quality with standard clinical dyes to confirm the health of your eye's surface. There is no stinging sensation when the dyes are applied.

7. Impression cytology for laboratory analysis of inflammatory markers. This requires use of topical anaesthetic eye drops (standard in clinical practice) which might sting slightly (for a few seconds) on instillation, then briefly touching a small, flat and minimally invasive collection pad (called the EYEPRIM®) onto the eye surface (which you won't feel).

Possible benefits

In taking part in this study, you will receive a full ocular surface review and can be provided with feedback about your ocular surface condition, without cost. You will also have the opportunity to trial

a therapy that might help your dry eyes, free of charge. Your contribution, together with those of others, will help us understand the true benefits of the various therapies for blepharitis and MGD. You will be offered a $20 MTA voucher at each visit in recognition of your time and to help offset travel costs in attending participant visits.

How the data will be used

This trial has received funding from TRG Natural Pharmaceuticals who are providing the roller ball applicators containing castor oil. Additional costs are being covered by the University. We will report the outcomes of the trial to our industry collaborators, but it's important to note that this is an investigator-initiated study, led by the researchers at the University of Auckland. The funder has no influence over the study design, conduct, analysis, interpretation or reporting. It is anticipated that the results of this study will be written up and presented orally, and may be presented at national and international conferences and submitted for publication in the scientific literature. You will not be individually identifiable in any report from the study. There is the possibility that your data could be combined with that from another research centre, so that it can be reported as a multicentre study. Any data used for this purpose will be entirely de-identified so that your identity cannot be traced from the data.

Participation

Participation in this study is voluntary which means you are under no obligation to take part. Neither your refusal nor agreement to take part will affect the clinical care you receive, from the researchers or any other clinicians, today or in the future. If you are a patient of the Eye Clinic, you may contact the Clinic Director should you feel that this assurance has not been met. Similarly, if you are a student at the University of Auckland, your decision to participate or not participate will not influence your academic progress in any way. As a student, you may contact your HoD should you feel that this assurance has not been met.

Eligibility

There are a number of reasons you might not be suitable for this project. These include:

- Regular use of eye medications or therapies (other than lubricant eye drops or warm compresses).
- Current use of lid hygiene products – these need to be stopped at least 2 weeks before the trial begins and for the duration of the trial.
- Significant disparity in the ocular surface condition between your two eyes. Both eyes need to be of similar severity at baseline for valid comparisons between techniques to be made.
- Contact lens wear – contact lens wearers are eligible as long as the contact lenses have been removed at least 24 hours previously, and must remain unworn for the duration of the study.
- Ocular surgery in the last 3 months in either eye
- A systemic condition, disease or trauma judged by the investigator to be incompatible with participation in the study
- The history or presence of any ocular disorder or condition in either eye that would likely interfere with the interpretation of the study results

Incidental Findings

Any abnormalities noted incidentally during the examination of your eye will be discussed with you and you will be offered advice about management and/or referral consistent with normal clinical care by registered health practitioners. If you do not wish to be advised of incidental findings, you will not be eligible to take part.

Data Storage/Retention/Destruction:

Clinical data (paper copies) will be stored in a secure cabinet at the University of Auckland for six years (for publication purposes) before being securely destroyed. Electronic data will be de-identified immediately following collection and stored indefinitely on password-protected computers to allow comparison to future data sets.

Consent Forms will be held by the Department in a secure location, separate from the research data for a period of six years.

Impression cytology samples collected to assess the level of eye surface inflammation are completely used up in the laboratory analysis and disposed of appropriately.

Right to Withdraw from Participation:

If you change your mind about participating, you have the right to withdraw from the study at any time, without providing a reason. You are also at liberty to withdraw any data traceable to you, up to two weeks after your final clinic appointment.

Anonymity and Confidentiality:

All participants will be assigned a unique alpha-numeric identification code to protect confidentiality. A document linking the code with your name will be stored independently of the clinical data and will be available only to the researchers. All clinical data will be collected, recorded, stored and analysed under your unique code. The linking document will be destroyed along with the raw clinical data after 6 years. If the results of this study are to be published in the scientific literature or presented at a conference, as with the study report, you will not be individually identifiable.

Risk of Harm

The risk of harm during the clinical assessments, is minimal, and is the same level of risk you would be exposed to a routine eye exam. The investigators are trained to carry out these procedures safely. You will be given detailed instructions during the test procedures to minimise risks as far as possible. The investigators are trained to anticipate patient movements, however, in the unlikely event you move suddenly or unexpectedly during the test procedure, there is a small risk that contact could be made with your eye surface, and an abrasion could occur. This would usually take several hours to fully resolve, during which time your eye could be slightly uncomfortable. The abrasion would be treated, and you would be followed up according to standard clinic protocols.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Contact Details and Approval:

For any queries or concerns about this study please contact one of the following researchers:

Prof Jennifer P. Craig (Principal Investigator)
Email: jp.craig@auckland.ac.nz
Research Mobile: 022 EYE PAIN (022 393 7246)

Ms Catherine Shon
Research optometrist
Email: catherine.shon@auckland.ac.nz

Dr Kalika Bandamwar
Postdoctoral research fellow
Email: kalika.bandamwar@auckland.ac.nz

Ms Carol D'Souza
BOptom summer student
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Professor Charles N. J. McGhee (Head of Department of Ophthalmology)
Email: c.mcghee@auckland.ac.nz
Telephone: 09 923 6712

For any queries regarding ethical concerns you may contact:

The Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711.
Email: humanethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 16/03/2018 FOR 6.5 YEARS, REFERENCE NUMBER 020783