ISRCTN93820838 https://doi.org/10.1186/ISRCTN93820838

Modern ‘over-the-counter’ treatments for dry eye and its’ associated conditions

Submission date 07/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 09/03/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/02/2022	**Condition category** Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Meibomian gland dysfunction (MGD) is the leading cause of dry eyes. It occurs when the glands around the eyelids become blocked and cannot release oil to the tears. MGD may be present with a parasite called Demodex, which is commonly found in skin and hair. It is believed Demodex may play a role in physically blocking the glands, reducing the supply of oil to the tears. The oily layer of our tears prevents the tears from evaporating and the front surface of the eye from drying out. When the supply of oil is being blocked then tears are prone to evaporating quickly causing common sensations of dryness, itch, irritation, gritty, burning sensation, blurred vision and the necessity to blink a lot. The normal treatment for a dry eye has been to place a warm face cloth over the eye area to try to release the oils. There are now over the counter eye masks available that are aimed to provide relief for dry eyes. Two common examples of these are the MGDRx Eyebag which is a dry heat mask made of natural materials and the OPTASE Moist Heat Mask which is a moist warm compress which absorbs moisture from the air and releases a natural moist relief for dry eyes. The aim of this study is to investigate and compare the effectiveness of the MGDRx EyeBag and OPTASE Moist Heat Masks as a treatment option for patients with MGD as well as look at the relationship between Demodex and MGD and how effective warm compresses are at treating Demodex infestation.

Who can participate?
Adults over the age of 18 with a MGD

What does the study involve?
After filling out a symptom questionnaire and having an eye exam, participants are randomly allocated to one of three groups. Those in the first group are instructed to place a warm face cloth over their eyes for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. Those in the second group are instructed to wear the MGDRx Eyebag for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. Those in the third group are instructed to wear the OPTASE Moist Heat Masks for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. All participants are asked to massage their eyelids for 30-40 seconds after using their treatments to increase the flow of oil to the tears. Participants are asked to attend the National Optometry Centre for four appointments during the study period, for an initial visit

and then three more visits every two weeks. The appointments take one hour and involve checking for Demodex, by removing two eyelashes from each lid of each eye, as well as measuring the severity of MGD.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in MGD symptoms and from an increase in knowledge about managing dry eyes. There is a small risk of receiving a burn from using heated compresses however participants are instructed on how to correctly avoid this.

Where is the study run from?
The National Optometry Centre, Dublin Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?
September 2016 to February 2019 (as of 04/10/2018)

Who is funding the study?
1. Dublin Institute of Technology (Ireland)
2. Scope Ophthalmics (Ireland)

Who is the main contact?
Orla Murphy
orla23murphy@gmail.com

Contact information

Type(s)
Public

Contact name
Ms Orla Murphy

ORCID ID
https://orcid.org/0000-0002-5390-0892

Contact details
The National Optometry Centre
Dublin Institute of Technology
19A Lower Kevin Street
Dublin
Ireland
8
+353 87127 8022
orla23murphy@gmail.com

Additional identifiers

Protocol serial number
3

Study information

Scientific Title
The efficacy of the MGDRx EyeBag and OPTASE Moist Heat Mask in comparison to traditional methods for the treatment of meibomian gland dysfunction and ocular Demodex folliculorum infestation

Study objectives
1. Both modern treatments will be more effective at treating MGD than the traditional warm face cloth method
2. There will be no significant difference in efficacy between the modern warm compresses for treatment of MGD
3. None of the treatments will be effective at treating ocular Demodex folliculorum infestation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dublin Institute of Technology Research Ethics Committee, 15/09/2014, ref: 14-45

Primary study design
Interventional

Study design
Single-centre double blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Meibomian gland dysfunction (MGD), Demodex folliculorum blepharitis, dry eye, ocular surface disease

Interventions
After filling out a symptom questionnaire and having an eye exam, participants are randomly allocated to one of three groups. Participants are randomised by choosing a number from 1-60. Each number corresponds with a treatment. Participants are unaware of the treatment they have chosen until they leave the practice and open their treatment pack.

Control group: Participants use a warm face cloth worn over the eye area for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. After each ten minute treatment the participants massage their eyelids for approximately 30-40 seconds to help unblock the glands and increase the flow of oil to the tears.

Treatment group 1: Participants use the MGDRx Eyebag worn over the eye area for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. After each ten minute treatment the participants massage their eyelids for approximately 30-40 seconds to help unblock the glands and increase the flow of oil to the tears.

Treatment group 2: Participants use the OPTASE Moist Heat Mask worn over the eye area for ten minutes twice a day for two weeks, and then once a day for ten minutes the following six weeks. After each ten minute treatment the participants massage their eyelids for approximately 30-40 seconds to help unblock the glands and increase the flow of oil to the tears.

The treatment takes two months overall. Participants compliance is monitored using treatment diaries. Each participant are asked to attend the National Optometry Centre for four appointments during the study period, for an initial visit and then three more visits every two weeks. The appointments do not take longer than one hour and involves checking for the presence of Demodex, by removing two eyelashes from each eye, one lash from the upper eyelid and one lash from the lower eyelid. The appointments also follow up on the participants MGD symptoms.

Intervention Type
Device

Primary outcome(s)
Meibomian Gland Dysfunction (MGD) grade/severity is measured according to recommendations of the diagnostic subcommittee of the International Workshop on Meibomian Gland Dysfunction at baseline, 2 weeks, 4 weeks and 8 weeks.

Key secondary outcome(s)
1. Association between MGD and ocular Demodex folliculorum infestion is assessed using prevalence of ocular Demodex folliculorum infestation in the lash samples at baseline
2. Effectiveness of warm compresses in treating ocular Demodex folliculorum infestation is assessing using the quantity of Demodex in lash sampels at baseline, 2 weeks, 4 weeks and 8 weeks

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Have G1 meibomian gland dysfunction according to the diagnostic subcommittee of the International Workshop on Meibomian Gland Dysfunction
2. Be 18 years of age or older

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Undergoing treatment for meibomian gland dysfunction, or have used treatment within the past 6 months
2. Contact lens wearers
3. Ocular surgery within the past 6 months
4. Systemic disease or use of topical/systemic medication known to affect the eyes
5. Presence of ocular disease except for MGD and blepharitis

Date of first enrolment
09/03/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin Institute of Technology
The National Optometry Centre
19A Lower Kevin Street
Dublin
Ireland
Dublin

Sponsor information

Organisation
Dublin Institute of Technology

ROR
https://ror.org/04t0qbt32

Funder(s)

Funder type
University/education

Funder Name
Dublin Institute of Technology

Funder Name
Scope Ophthalmics

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/11/2019	15/02/2022	Yes	No
Participant information sheet		07/03/2017	14/03/2017	No	Yes