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Eyelid massager effectiveness in meibomian gland dysfunction

Submission date
06/02/2017

Recruitment status
No longer recruiting

Registration date
21/02/2017

Overall study status
Completed

Last Edited
14/03/2017

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dry eye disease is a common medical condition that occurs when the eyes do not make enough tears or the tears evaporate too quickly. This leads to the eyes becoming dry, red, and irritated. Symptoms include dryness, grittiness, soreness, burning, and temporarily blurred vision which usually improves after blinking. Blinking naturally helps express meibum (oil) from healthy meibomian glands in the eyelids. If these glands are blocked, the eyes become dry and the glands may eventually atrophy (waste away). Treatment to unblock the glands involves eyelid massage. This encourages meibum to flow from the glands and allows the eye surface to function normally. Clinical evidence indicates that tear film stability can be improved by expression of the meibomian glands by eyelid massage. However, there is a need for a hygienic and effective eyelid-massaging tool. Anecdotal evidence suggests that dry eye patients most frequently use their fingers to massage their eyelids in an incorrect and ineffective manner and this is one of the first studies to address this issue. The aim of this study is test an eyelid-massaging device along with a heated eye mask over a period of 3 months.

Who can participate?
Patients aged 18 or over with dry eye disease due to meibomian gland dysfunction

What does the study involve?
Participants are randomly allocated into two groups. Participants in the test group use an 'Eyepeace' eyelid massager along with a heated eye mask once daily for a period of 3 months. Participants in the control group use a non-heated (room temperature) eye mask once daily for a period of 3 months. The participants can keep the eyelid massager and the eye mask after the end of the study. All participants undergo eye examinations at the start of the study and after 2 weeks, 1 month, 2 months and 3 months.

What are the possible benefits and risks of participating?
The results will increase knowledge of dry eye disease which may benefit people in the future. Eyelid massage and heated eye masks are a safe and non-invasive technique to improve eye health. An allergy questionnaire is used at the start of the study to help identify and minimise any possible risks.

Where is the study run from?
Cathedral Eye Clinic (UK)

When is the study starting and how long is it expected to run for?
April to November 2017

Who is funding the study?
Cathedral Eye Clinic (UK)

Who is the main contact?
Prof. Jonathan Moore

Study website
www.cathedraleye-research.co.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v-3

Study information

Scientific Title
Investigating the efficacy of the Eyepeace eyelid massager in patients with meibomian gland dysfunction related evaporative dry eye

Study objectives

Dry eye that occurs in patients with meibomian gland dysfunction is secondary to increased evaporation associated with decreased function of meibomian glands. Therefore expression of the meibomian glands with the Eyepeace eyelid massager will improve their dry eye condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized parallel-assigned single-blind (investigator) treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
Participants are randomised by random number generation to one of two groups (the researcher who tests the patients will not know whether they belong to the study group or control group):
1. Participants receive an 'Eyepeace' eyelid massager and heated eye mask (2 mins in a warm cup of water) on both eyes (test group) once daily
2. Participants receive a non-heated eye mask (control group) and use it once daily.
All participants are instructed to use the treatment at the same time (morning) for 3 months. All participants undergo eye examinations at enrolment, baseline, and 2 weeks, 1 month, 2 months and 3 months after starting treatment.

Intervention Type
Device

Primary outcome measure
1. Tear film lipid layer thickness for right and left eyes, measured using images captured with Tearscope at 2 weeks, 1 month, 2 months and 3 months

Secondary outcome measures
Measured at baseline, 2 weeks, 1 month, 2 months and 3 months:
1. Tear film quality, measured as non-invasive tear break up time using a slit-lamp-mounted

TearScope on each eye in random order
2. Meibomian gland function, based upon meibum quality and expressibility using a slit-lamp following firm digital pressure to the eyelid margins
3. Ocular redness/hyperaemia, measured using images captured non-invasively using a digital slit-lamp photography of the limbal and temporal conjunctiva for both eyes
4. Tear osmolarity for right and left eyes, measured using TearLab
5. Corneal sensitivity for right and left eyes, measured using handheld esthesiometer (Cochet-Bonnet)
6. Corneal staining for right and left eyes, assessed via instillation of lissamine green and fluorescein sodium and using the Oxford corneal grading score
7. Dry eye symptoms for right and left eyes, measured using the Ocular Surface Disease Index
8. Visual satisfaction, measured with Quality of Vision (QOV) questionnaire scores
9. Longitudinal progress of the patient's dry eye symptoms and adherence to dry eye treatment, measured with the D-III questionnaire

Overall study start date
01/04/2017

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Have otherwise healthy eyes
3. Are prepared not to wear contact lens for 3 months of the trial
4. Have a NITBUT <10s
5. OSDI score: greater than or equal to 12
6. Symptom frequency at least "some of the time"
7. Presence of cloudy fluid expressed from at least 1 of the central 8 glands on the lower/upper lid AND/OR presence of poor expressibility from at least 2-3 of the central 8 glands on the lower lid

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 total; 50 participants test group, 50 participants control group. Taking into consideration the possibility of 10-15 dropouts participants in each group.

Key exclusion criteria
1. Conjunctivitis
2. Meibomian cysts
3. Styes
4. Damage to the cornea
5. Ocular injury
6. Cataract or laser refractive surgery in the past 6-months
7. Increased intraocular pressure (primary or secondary)
8. Any chronic disease of the eye

Date of first enrolment
01/06/2017

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Cathedral Eye Clinic
Belfast
United Kingdom
BT1 2LS

Sponsor information

Organisation
Cathedral Eye Clinic

Sponsor details
89-91 Academy Street
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cathedral Eye Clinic

Results and Publications

Publication and dissemination plan
The researchers of this study plan to publish the results in a health journal so others can read about and learn from the results of the study.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jonathan Moore.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		20/02/2017	14/03/2017	No	Yes