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Evaluation of combined Eyepeace and Eye Nutrients study

Submission date	Recruitment status	[X] Prospectively registered
09/02/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/02/2018	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Inflammation can occur after laser or eye surgery, which can disrupt the tear film and eye surface and lead to short- or long-term dry eye syndrome, where the eyes do not make enough tears or the tears evaporate too quickly. This causes the eyes to become dry, red, and irritated. Reducing the inflammation can allow the eye surface to function normally. Blinking naturally helps express meibum (oil) from healthy meibomian glands in the eyelids. If these glands are blocked, the eyes become dry and inflamed. Treatment to unblock the glands involves eyelid massage. Tear film stability can be improved by expression of the meibomian glands by eyelid massage and consuming omega fatty acid supplements. However, there is a need for a hygienic and effective eyelid-massaging tool. Dry eye patients most frequently use their fingers to massage their eyelids in an incorrect and ineffective manner. Eyepeace is a new, unique, CE-marked medical device, designed to combat the issues of dry eye due to meibomian gland dysfunction. It is specially designed to be a non-invasive way to massage the meibomian glands, resulting in the treatment and prevention of dry eye. Anecdotal evidence suggests that patients experience improvements in symptoms after taking omega fatty acid supplements. This study aims to test the effects of combined use of Eyepeace (eyelid massager) for expressing the meibomian glands and oral Eye Nutrients (omega fatty acid supplements) for reducing eye surface inflammation over 3 months. Eye Nutrients has a unique blend of omega fatty acids, chosen to reduce inflammation of the eye surface.

Who can participate?
Patients aged 18 or over undergoing laser and/or intraocular lens (IOL) refractive surgery

What does the study involve?
Participants are randomly allocated to one of three groups. Group A uses the Eyepeace eyelid massager once a day from 1 week before surgery until the day before surgery, and also take Eye Nutrients, two capsules a day, from 1 week before surgery until 3 months after surgery. Group B takes Eye Nutrients only as described above. Group C does not use Eyepeace or Eye Nutrients. All participants undergo eye tests at the start of the study and 3 months after starting treatment.

What are the possible benefits and risks of participating?
There is no direct benefit to participants from being in this study. However, their participation may help others with dry eye in the future because of knowledge gained from this research. There are no risks associated with gently massaging the eyelids, consuming monitored omega fatty acid supplements and completing eye tests at the clinic. All tests on the eyes are general eye examinations performed by trained professionals.

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

When is the study starting and how long is it expected to run for?
March 2018 to July 2018

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

Who is the main contact?
Prof. Jonathan Moore

Contact information

Type(s)
Scientific

Contact name
Prof Jonathan Moore

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18/CER/EPEN1

Study information

Scientific Title

Investigate the improvements in tear film/ocular surface and visual recovery in laser and intraocular lens (IOL) refractive surgery patients preoperative using the Eyepeace (Eyelid massager) and Eye Nutrients (omega fatty acid supplement)

Acronym
EPEN

Study objectives
Symptoms of dry eye due to transient tear film disruption can occur in most patients post laser and intraocular lens (IOL) refractive surgery. Therefore expression of the meibomian glands with the 'Eyepeace' eyelid massager and consumption of 'Eye Nutrients' omega fatty acids will improve their 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) trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Dry eye

Interventions
Participants are randomised 1:1:1 by random number generation to one of three groups (the researcher who tests the patients will not know whether they belong to the study group A, study group B, or control group):

Treatment for Group A:
Eyepeace eyelid massage: once a day, to be started 1 week prior to laser or intraocular lens

surgery, to be stopped one day prior to surgery
Eye nutrients: two capsules a day, to be started 1 week prior to laser or intraocular lens surgery, to be stopped 3 months after surgery

Treatment for Group B:
Eye nutrients: two capsules a day, to be started 1 week prior to laser or intraocular lens surgery, to be stopped 3 months after surgery

Treatment for Group C:
No Eyepeace or Eye nutrients

All participants undergo eye examinations at enrolment, baseline and 3 months after starting treatment.

Intervention Type
Mixed

Primary outcome measure
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, 1 month 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 high resolution digital slit-lamp photography of the limbal and temporal conjunctiva for both eyes. Ocular surface conjunctival blood-flow will also be observed and correlated with the heart beat /pulse of the patient
4. MMP-9, an inflammatory marker in the tears of patients with dry eye disease for right and left eyes, measured using a non-invasive RPS InflammaDry Detector
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. Tear volume for right and left eyes, measured using Phenol red thread test
8. Dry eye symptoms for right and left eyes, measured using the Ocular Surface Disease Index
9. Visual satisfaction, measured with Quality of Vision (QOV) questionnaire scores
10. 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
01/03/2018

Completion date
01/07/2018

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
225

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
01/03/2018

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Cathedral Eye Clinic
Belfast
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BT1 2LS

Sponsor information

Organisation
Cathedral Eye Research

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cathedral Eye Research

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2018

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