

Evaluation of combined Eyepeace and Eye Nutrients study

Submission date 09/02/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 14/02/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/02/2018	Condition category Eye Diseases	☐ Individual participant data ☐ 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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89-91 Academy Street
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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized parallel-assigned single-blind (investigator) trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 InflammDry 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

Northern Ireland

Study participating centre

Cathedral Eye Clinic

Belfast

United Kingdom

BT1 2LS

Sponsor information**Organisation**

Cathedral Eye Research

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Results and Publications

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