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Effects of contact and non-contact laser photocoagulation therapy on ocular surface in patients with proliferative diabetic retinopathy

Submission date
28/02/2016

Recruitment status
No longer recruiting

Registration date
24/03/2016

Overall study status
Completed

Last Edited
24/03/2016

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Diabetes is a serious long-term condition where a person is unable to control their blood sugar (glucose). People living with diabetes often have to live with long-term complications of the disease. One of these complications is diabetic retinopathy, where the tiny blood vessels (capillaries) that supply cells at the back of the eye (the retina) that are sensitive to light become damaged over time. There are four distinct stages of diabetic retinopathy, the most advanced of which being proliferative diabetic retinopathy (PDR). Over time, the capillaries become so damaged that growth factors (chemicals that trigger growth) are released, causing new blood vessels start to grow behind the retina. These blood vessels are generally very weak and prone to leakage, distorting the vision. Laser photocoagulation (LP) is a surgical technique used to treat PDR. This involves using the heat from a laser to seal or destroy the abnormal, leaking blood vessels in the retina. Although the procedure is very effective, it has been known to cause ocular surface disease (OSD). This is whether the surface of the cornea (the transparent layer that forms the front of the eye) is damaged, causing dry eyes, blurry vision and discomfort. The LP procedure can either be contact LP, in which the laser makes direct contact with the eye surface via a contact lens, or non-contact LP, in which the eye in held open and the laser is applied from a short distance. Both of these techniques have their risks and benefits however it is not known which is least likely to cause OSD. The aim of this study is to find out whether the contact LP or non-contact LP technique causes a higher rate of OSD in PDR patients.

Who can participate?
Adults aged 40 and over who have recently been diagnosed with proliferative diabetic retinopathy.

What does the study involve?
At the first study visit, all participants complete a questionnaire and have an eye examination. Participants are randomly allocated to one of two groups. Those in the first group undergo contact LP, which involves receiving numbing eye drops five minutes before the procedure before the contact lens used for the procedure is placed on the eye. The laser therapy is then completed while patients are in a sitting position. Those in the second group undergo non-

contact LP, which involves receiving numbing eye drops five minutes before the procedure before an eye speculum (device to hold the eye open) is put in place. The laser therapy is then delivered while the patient is lying down on a treatment couch. For both groups, the therapy is completed three times spaced one week apart. Three months after the final laser therapy session, participants in both groups repeat the initial evaluations in order to find how many are suffering from OSD.

What are the possible benefits and risks of participating?
Participants benefit from receiving the treatments free of charge, and undergoing the laser therapy could lead to an improvement in their vision. Risks of participating in this study are small but include the possibility of discomfort during the eye examinations at the start and end of the study. For most people, undergoing LP does not cause serious complications, however there is a risk that participants may experience discomfort and blurred vision for at least four to six hours after the procedure.

Where is the study run from?
Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
June 2012 to May 2015

Who is funding the study?
Universiti Sains Malaysia (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised paralell trial looking at the effects of contact and non-contact laser photocoagulation therapy on ocular surface in patients with proliferative diabetic retinopathy

Study objectives
Contact laser photocoagulation is related with higher incidence of dry eyes compared to non-contact laser photocoagulation in proliferative diabetic retinopathy patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethical Committee, School of Medical Sciences, Universiti Sains Malaysia, 23/05 /2013, ref: USMKK/PPP/JEPeM [263.3.(6)]

Study design
Single-centre prospective randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Proliferative diabetic retinopathy

Interventions
Eligible eyes are randomized into two treatment groups using a random sampling envelope technique. For all participants, once baseline parameters have been obtained, laser eye therapy is given. The eyes are dilated using 1% tropicamide eyedrops 20 minutes before laser therapy before laser therapy delivered at week 1, week 2 and week 3, with total laser shots of 3000-5000 shots.

Contact laser photocoagulation group: Patients receive a single drop of 0.5% proparacaine hydrochloride topical anaesthesia solution 5 minutes before the placement of the applanation contact lens. A coupling fluid (2.5% methylcellulose) and contact lens are used for contact LP. Patients are seated at Argon laser slit lamp machine. In the slit-lamp biomicroscope, the delivery of Argon green laser is transcorneal. The laser is delivered to the retina using the Mainster Wide Field contact lens or Goldmann's three-mirror contact lens with the patient sits at a slit-lamp with laser fibreoptic cable.

Non-contact laser photocoagulation group: Laser therapy is delivered to retina via binocular indirect laser delivery system. Patient receive a single drop of 0.5% proparacaine hydrochloride topical anaesthesia solution 5 minutes before the procedure. Patient are instructed to lie down on a treatment couch in supine position while an eye speculum is inserted. Artificial tears eyedrops are instilled intermittently to keep the ocular surface moist. The laser is delivered to retina with the aid of a 20D or 30D condensing lens.

Following completion of 3 sessions of laser therapy, participants are followed up 3 months post intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Schirmer test value is measured using the Schirmer test at baseline and 12 weeks
2. Tear film break-up time (TBUT) is determined by measuring the interval between the last complete blink and the first appearance of a dry spot in the stained cornea at baseline and 12 weeks
3. Ocular Surface Disease Index (OSDI) score is measured using the OSDI questionnaire at baseline and 12 weeks

Secondary outcome measures
N/A

Overall study start date
01/06/2012

Completion date
30/05/2015

Eligibility

Key inclusion criteria
1. Aged 40 years and over
2. Newly diagnosed proliferative diabetic retinopathy among diabetic patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Required 60 patients (30 eyes for each group).

Key exclusion criteria
1. On regular eye drops medication (eg topical antiglaucoma drugs)
2. Poor media that obscuring view of delivering laser photocoagulation to the retina such as corneal opacity and preretinal or vitreous hemorrhage obscuring view of retina
3. Previous history of intraocular surgery or ocular trauma including chemical, thermal or radiation injury
4. Contact lens wearer
5. Previous history of laser photocoagulation

Date of first enrolment
01/06/2013

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Sains Malaysia
School of Medical Sciences
Health Campus
Kubang Kerian
Malaysia
16150

Sponsor information

Organisation
Universiti Sains Malaysia

Sponsor details
School of Medical Sciences
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Sponsor type
University/education

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
Universiti Sains Malaysia

Results and Publications

Publication and dissemination plan
Paln to publish in PLOS ONE journal for the effect of contact and non-contact laser photocoagulation therapy on ocular surface.

Intention to publish date
01/04/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request