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Optic nerve head and ocular changes associated with micropulse diode laser in diabetic macular edema

Submission date 20/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/11/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/10/2015	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes results in fluid leakage and swelling of the retina of the eye. This is called diabetic macular edema and can lead to loss of vision. Recently, the gold standard treatment changed from laser surgery to intraocular (eye) injections. Patients who do not want this this treatment may undergo treatment with a subthreshold micropulse diode laser. We're examining the safety and effectiveness of this treatment by looking at changes at a part of the eye called the optic nerve head. If there is thinning at the nerve fiber layer at the optic nerve head, the safety of the treatment may be called into question. A reduction in scarring or improvement in vision would show the effectiveness of the treatment. The aims of this study are to determine the effect of this treatment on the nerve fiber layer of the optic nerve head, and to find out whether this treatment reduces the swelling of the retina and improves the patient's vision . The final aim is to determine whether this treatment is a feasible alternative to (or replacement for) the current gold standard of clinical practice.

Who can participate?
Patients over 18 years of age with diabetic macular edema who have opted out of the conventional treatment of intraocular injections.

What does the study involve?
All participants receive the same treatment of subthreshold micropulse diode laser. In addition to the standard treatment we also perform an extra scan of the patients' eye in order to compare the patients' retinal thickness, optic nerve head nerve fiber layer thickness, and vision before treatment and 3 and 6 months after treatment.

What are the possible benefits and risks of participating?
Patients who have opted for subthreshold micropulse diode laser treatment will avoid the inconvenience, risk and discomfort of regular intraocular injections. They may also see a reduction in their diabetic macular edema and retinal thickness while seeing an improvement in vision. Furthermore, we will find out if optic nerve changes occur as a result of the alternative treatment. Many studies have shown the safety of eye scans and patients will not be exposed to

radiation. The extra time involved for the additional eye scans would be an extra 2 minutes for each eye affected for each visit. The patients do not need to make any additional visits for the study. The alternative treatment being used has been proven safe in previous studies and does not cause visible retinal burns, but there is a risk that the treatment may not be effective, which could allow diabetic macular edema to progress. These risks also occur in conventional treatment.

Where is the study run from?
University Hospital of Northern British Columbia (Canada).

When is the study starting and how long is it expected to run for?
December 2012 to December 2013.

Who is funding the study?
Northern Medical Program of the University of British Columbia (Canada).

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
Optic nerve head and ocular changes associated with micropulse diode laser in diabetic macular edema: a cohort study

Study objectives
To determine whether the nerve fiber layer of the optic nerve head is reduced in patients with diabetic macular edema undergoing treatment with subthreshold micropulse diode laser therapy. Any thinning of the nerve fiber layer at the optic nerve head would suggest the therapy is harmful. Further, we will look at other ocular parameters in patients receiving treatment, including visual acuity and retinal thickness as measured by optical coherence tomography. Any reduction in retinal thickness or associated improvement in visual acuity would suggest the therapy is effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia Rise Application System - approval pending

Study design
Single-center prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact bhupinder.johal@alumni.ubc.ca to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetic macular edema

Interventions
The standard procedure for diabetic macular edema is to
1. Go through the options available such as intraocular injections or subthreshold micropulse diode laser therapy
2. If Micropulse is chosen, go through the consent form
3. Give a date for the therapy
4. Perform a Optic Coherence Tomography Scan (OCT) of the macula
5. Perform the therapy
6. See patient after 3 months and perform another OCT scan of the macula
7. Repeat laser therapy if necessary
8. The final OCT scan of the macula

During this study, the steps would remain the same; however, when performing the OCT scan of the macula, we will also perform an OCT scan of the optic nerve head. The extra scan will take 2 minutes an eye and many studies have been published showing the safety of such a scan. Further, no radiation exposure will be administered by doing such a scan. The OCT scan of the optic nerve head is the only research related procedure that will differ from the standard care.

The extra time involved for patients required would be an extra 2 minutes for each eye affected for each visit. This would result in an additional four OCT scans and in a 6 month period, an additional 8 minutes total. The patient would not need to have any additional visits to accommodate the study and from start to finish, it would be about 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Optic nerve head nerve fiber layer thickness measured by optical coherence tomography measured pre-laser, 3 months and 6 months

Secondary outcome measures
1. Visual Acuity using Snellen Visual Acuity Chart
2. Retinal Thickness using optical coherence tomography

Measured pre-laser, 3 months and 6 months

Overall study start date
01/12/2012

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Type I or type II diabetes mellitus
2. Clinically significant macular edema (confirmed by optical coherence tomography)
3. HbA1 < 10.0
4. Blood pressure < 160/100 mm Hg
5. Age > 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Proliferative diabetic retinopathy
2. Retinal detachment
3. Significant media opacities
4. Previous retinal or intraocular surgery
5. Glaucoma or other ocular diseases interfering with the assessment of the results
6. Cataract extraction or lens implantation in the previous 12 months
7. Preretinal or vitreous haemorrhage

Date of first enrolment
01/12/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Canada

Study participating centre
University of Northern British Columbia
Prince George
Canada
V2N 4Z9

Sponsor information

Organisation
University of Northern British Columbia (Canada)

Sponsor details
3333 University Way
Prince George
Canada
V2N 4Z9

Sponsor type
University/education

Website
http://www.unbc.ca

ROR
https://ror.org/025wzwv46

Funder(s)

Funder type
University/education

Funder Name
University of Northern British Columbia (Canada) - Northern Medical Program

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration