

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	☒ 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 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?

Dr Andrew Lukaris

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Contact information

Type(s)

Scientific

Contact name

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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

Primary study design

Observational

Study design

Single-center prospective cohort study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Measured pre-laser, 3 months and 6 months

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/025wzww46>

Funder(s)

Funder type

University/education

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration