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A comparison of standard laser with micropulse laser for the treatment of diabetic macular oedema

Submission date
02/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
15/08/2025

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetic retinopathy is the damage of the retina (the light-sensitive tissue lining the back of the eye) caused by diabetes. People with diabetic retinopathy may lose vision as a result of them developing what is called diabetic macular oedema (DMO). DMO is the most common complication of diabetes in the back of the eye. In DMO, fluid leaks in the centre of the retina (macula). The accumulation of this fluid reduces the vision, as the retina needs to be dry to work properly. If the fluid is left untreated, permanent and irreversible visual loss will occur. The amount of fluid in the macula can be measured by doing a scan of the eye called optical coherence tomography (OCT). Depending on the amount of fluid present in the macula, people with DMO will be offered medicines known as anti-vascular endothelial growth factor (anti-VEGF) or laser treatment. The National Institute of Health and Care Excellence (NICE) found that laser treatment was effective in people with DMO and retinas that had been thickened by fluid but below to a certain limit (when the centre of the retina is less than 400 microns in thickness as measured by the OCT) and offers good value for money compared to anti-VEGF injections. Both, standard laser and micropulse laser, are being used currently in ophthalmic clinics across the world. The aim of this study is to compare the effectiveness of these two lasers in the treatment of patients with DMO.

Who can participate?
Adults who have diabetic retinopathy and DMO.

What does the study involve?
At the start of the study, all participants have an eye examination and have a sample of blood taken to check their blood sugar control. In addition, their medical history is taken and participants fill in some questionnaires about how they perceive their sight and how their sight may affect their life. Participants are then randomly allocated to one of two groups. Those in the first group are treated with the micropulse laser and those in the second group are treated with the standard laser. The participants do not know which laser they are being treated with. Participants in both groups attend clinic appointments after four, eight, 12, 16, 20 and 24 weeks so that the effects of the treatment can be assessed.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Royal Victoria Hospital, Belfast and 15 other NHS hospitals (UK)

When is the study starting and how long is it expected to run for?
April 2016 to May 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Lynn Murphy
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2016-003804-29

ClinicalTrials.gov (NCT)
NCT03690050

Protocol serial number
CPMS 33318, Protocol number: 16028NL-AF

Study information

Scientific Title
Diabetic Macular Oedema and Diode Subthreshold Micropulse Laser (DIAMONDS): A pragmatic, multicentre, allocation concealed, prospective, randomised, non-inferiority double-masked trial

Acronym
DIAMONDS

Study objectives
The aim of this study is to evaluate the clinical effectiveness and cost-effectiveness of Diode Subthreshold Micropulse Laser (DSML), when compared with standard threshold laser, for the treatment of patients with Diabetic Macular Oedema (DMO) with a central retinal subfield thickness of (CST) of <400 microns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland- HSC REC A, 17/08/2016, ref: 16/NI/0145

Study design
Randomized; Interventional; Design type: Treatment, Other

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants are randomised to one of two groups in a 1:1 ratio by an automated randomisation system to generate the random allocation sequence.

Intervention group: Participants undergo treatment with the micropulse laser. This involves the use of a laser technology aimed at minimising damage (“tissue-sparing”) to choroid and retina but maintaining treatment efficacy by its selective effect on the retinal pigment epithelium (RPE). It is performed using a laser that, instead of delivering a continuous-wave laser beam, as the standard laser, it provides very small, repetitive, low energy pulses of laser separated by a brief rest period. This rest period allows the tissue to cool down between laser pulses avoiding the increased tissue heat that would be produced by continuous laser and allowing the use of lower laser energy power to achieve an effect. The reduced heat produced in the tissue and the reduced energy power required for the treatment may reduce side effects. Specifically, the technology does not appear to cause retinal burns or scars associated with decreased retinal sensitivity in treated areas.

Control group: Participants receive standard treatment. This involves the use of standard threshold laser with any of the devices used currently for this purpose (e.g. frequency-doubled neodymium-doped yttrium aluminium garnet (Nd:YAG) 532 nm laser, argon laser, diode [561nm or IQ (577nm)] laser. Standard laser is applied to areas of thickened retina, macular non-perfusion and leaking microaneurysms, in accordance the modified ETDRS technique.

At baseline and again after 4, 8, 12, 16, 20, 24 months, participants undergo an opthamological examination and OCT scan to establish their eligibility for the study and to determine the

changes to their eye following laser treatment. Health and vision related quality of life will be evaluated through the use of the EQ-5D -5L, the NEI VFQ-25 and the VisQoL which will be obtained t baseline and months 12 and 24.

Intervention Type
Procedure/Surgery

Primary outcome(s)
BCdVA in the study eye is assessed by a BCdVA test (using ETDRS visual acuity charts at 4 meters) at baseline and months 4,8,12,16,20 and 24.

Key secondary outcome(s))
1. Binocular BCdVA is assessed by a binocular BCdVA test (using ETDRS visual acuity charts at 4 meters) at baseline and 24 months
2. Central subfield retinal thickness, as determined by spectral domain OCT at baseline and 24 months
3. Mean deviation (MD) of the Humphrey 10-2 visual field is assessed by a Humphrey 10-2 visual field test at baseline, 12 and 24 months
4. Percentage (%) of people meeting driving standards is assessed by an Esterman binocular visual field test at baseline and 24 months
5. Visual functioning (NEI VFQ-25), general health (EQ-5D-5L) and vision and quality of life (VisQol) are measured using NEI VFQ25, EQ-5D 5L and VisQoL questionnaire scores at baseline and 24 months
6. Incremental cost per quality-adjusted life year (QALY) gained is assessed by a Markov model based cost-utility analysis which will extend beyond the trial analysis period to estimate the longer-term cost-effectiveness, with costs and benefits discounted at 3.5%. The model will be populated by data from the trial and supplemented by estimates of effectiveness, quality of life and costs from published literature and expert opinion.
7. Side effects are measured by a review of the participant's medical and ophthalmic history at 4, 8, 12, 16, 20, 24 months
8. Number of laser treatments needed is assessed by the treating ophthalmologist at 4, 8, 12, 16, 20, 24 months
9. Use of additional treatments (other than laser) is assessed by the treating ophthalmologist at 4, 8, 12, 16, 20, 24 months

Completion date
31/05/2021

Eligibility

Key inclusion criteria
Patients with diabetic retinopathy and centre involving DMO, as determined by using spectral domain optical coherence tomography (SD-OCT), in one or both eyes with:
1. Central retinal subfield thickness of >300 but <400 microns as determined by SD-OCT due to diabetic macular oedema
OR
2. Central retinal subfield thickness of <300 microns provided that intraretinal and/or subretinal fluid is present in the central subfield (central 1 mm) related to diabetic macular oedema
AND
3. Visual acuity of >24 Early Treatment Diabetic Retinopathy Study (ETDRS) letters (Snellen equivalent > 20/320)

4. Amenable to laser treatment, as judged by the treating ophthalmologist
5. Over 18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
266

Key exclusion criteria
Eyes of patients will not be included in the study if:
1. The macular oedema is due to causes other than diabetic macular oedema such as epiretinal membrane, vitreomacular traction, vein occlusion, or others
2. The eye is ineligible for macular laser treatment, as judged by the treating ophthalmologist
3. The eye has DMO and central subfield retinal thickness (CST) of >400 microns.
4. The eye has active proliferative diabetic retinopathy (PDR) requiring treatment.
5. The eye has received intravitreal Anti- Vascular Endothelical Growth Factor (Anti-VEGF) therapy within the previous two months.
6. The eye has received macular laser treatment within the previous 12 months.
7. The eye has received intravitreal injection of steroids.
8. The eye has received cataract surgery within the previous six weeks
9. The eye has received panretinal photocoagulation within the previous 3 months

The patient:
1. Is on pioglitazone and the drug cannot be stopped 3 months prior to entering into the trial and for the duration of the study
2. Has chronic renal failure requiring dialysis or kidney transplant
3. Has any other condition that in the opinion of the investigator would preclude participation in the study (such as unstable medical status or severe disease that would make it difficult for the patient to be able to complete the study)
4. Has very poor glycemic control and started intensive therapy within the previous 3 months
5. Will use an investigational drug during the study

Date of first enrolment
18/01/2017

Date of final enrolment
18/12/2018

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Study participating centre
Royal Victoria Hospital, Belfast
Belfast Health & Social Care Trust
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD

Study participating centre
The John Radcliffe Hospital
Oxford Eye Hospital
Headley Way
Oxford
United Kingdom
EC1V 2PD

Study participating centre
Manchester Royal Eye Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Sunderland Eye Infirmary
Queen Alexandra Road
Sunderland
United Kingdom
SR2 9HP

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Bristol Eye Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LX

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
Royal Hallamshire Hospital
Directorate of Opthalmology
Glossford Road
Sheffield
United Kingdom
S10 23F

Study participating centre
King's College Hospital
Normandy Building
Denmark Hill
London

United Kingdom
SE5 9RS

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Hinchingbrooke
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Hull and East Yorkshire NHS Trust
Anlaby Road
Hull
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HU3 2JZ

Study participating centre
Stoke Mandeville Hospital
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Belfast Health & Social Care Trust

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 30/05/2022:
The datasets generated and/or analysed during the current study will be available upon request following the publication of the primary and secondary outcomes. Formal requests for data should be made in writing to Prof. Noemi Lois (Chief Investigator) via the NICTU (info@nictu.hscni.net). Requests will be reviewed on a case by case basis in collaboration with the Sponsor.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository the MACRO Database (https://nictu.hscni.net/Macro/)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	01/12/2022	06/02/2023	Yes	No
Protocol article		12/02/2019		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-effectiveness analysis	18/10/2023	19/10/2023	Yes	No
Participant information sheet	version V3	29/11/2016	19/05/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes