DIAMONDS Eligibility Summary

The study aims 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 (CST) of < 400 microns.

Please confirm eligibility of the participant with your principal investigator.

Inclusion

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 ETDRS letters (Snellen equivalent > 20/320)
4) Amenable to laser treatment, as judged by the treating ophthalmologist
5) Over 18 years of age

Exclusion

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 is:

10) Patients on pioglitazone and the drug cannot be stopped 3 months prior to entering into the trial and for the duration of the study
11) The patient has chronic renal failure requiring dialysis or kidney transplant
12) The patient 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)
13) The patient has very poor glycemic control and started intensive therapy within the previous 3 months
14) The patient will use an investigational drug during the study

Informed consent
Baseline assessments
Confirm eligibility
Blood sample for HbA1c*
Randomise
Patient questionnaires

*If no previous HBA1c (within the previous three months from baseline)

Standard care

Standard threshold laser (argon or frequency-doubled neodymium-doped yttrium aluminium garnet (Nd:YAG) 532 nm laser)

Intervention

Diode 577 nm subthreshold micropulse laser (DSML)

Follow Up Visits

Months 4,8,12,16,20 & 24

Analysis