Micropulse diode vs conventional green laser treatment in clinically significant diabetic macular oedema

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
25/07/2007		☐ Protocol		
Registration date		Statistical analysis plan		
30/08/2007	Completed	[X] Results		
Last Edited 28/09/2009	Condition category Eve Diseases	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number MP1

Study information

Scientific Title

Study objectives

Micropulse diode laser has been used for patients with clinically significant diabetic macular oedema. It has not been directly compared with the standard treatment with green laser. In this study, we are going to perform a prospective randomised double-masked controlled trial to compare these two treatment modalities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East London Ethical Committee, approved on 14 August 2003 (ref: 07-03-159)

Study design

Prospective randomised double-masked controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic macular oedema

Interventions

Micropulse diode vs conventional green laser treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Visual acuity at 12 months.

Key secondary outcome(s))

The following will be assessed at 12 months:

- 1. Contract sensitivity
- 2. Central retinal thickness
- 3. Visible laser scars in macula

Completion date

01/01/2007

Eligibility

Key inclusion criteria

- 1. Patients with clinically significant macular edema due to diabetes in at least one eye
- 2. Able to understand and consent to the study
- 3. Vision acuity on study eye better than 20/200

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

- 1. Ocular surgery within the past 6 months
- 2. Any laser surgery in the study eye
- 3. Any other ocular diseases in the study eye that can alter vision during the study period
- 4. Poor diabetic control with HBA1c >12

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Laser and Retinal Research Unit

London United Kingdom SE5 9RS

Sponsor information

Organisation

King's College Hospital (UK)

ROR

https://ror.org/01qz4yx77

Funder(s)

Funder type

Government

Funder Name

Ophthalmic Fund within the King's College Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009		Yes	No