ISRCTN90646644 https://doi.org/10.1186/ISRCTN90646644

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Victor Chong

Contact details
Laser and Retinal Research Unit
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS
victor@eretina.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Visual acuity at 12 months.

Secondary outcome measures
The following will be assessed at 12 months:
1. Contract sensitivity
2. Central retinal thickness
3. Visible laser scars in macula

Overall study start date
01/01/2005

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

Age group
Not Specified

Sex
Both

Target number of participants
100

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
England

United Kingdom

Study participating centre
Laser and Retinal Research Unit
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital (UK)

Sponsor details
Denmark Hill
London
England
United Kingdom
SE5 9RS
victor.chong@kch.nhs.uk

Sponsor type
University/education

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

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

Study outputs

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