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A prospective, randomised, double-masked, controlled trial of the treatment of diabetic maculopathy using diode micropulsed laser versus standard argon laser

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/09/2015	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr John Shilling

Contact details
Ophthalmology
Ground Floor, South Wing (Block 7)
St. Thomas' Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013146051

Study information

Scientific Title
A prospective, randomised, double-masked, controlled trial of the treatment of diabetic maculopathy using diode micropulsed laser versus standard argon laser

Study objectives
Is the use of micropulsed diode laser application more effective than current argon laser in treatment of diabetic maculopathy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Macular retinopathy

Interventions
Laser application in a grid/ focal pattern to patients with macula oedema secondary to diabetic retinopathy.

Intervention Type
Procedure/Surgery

Primary outcome measure

Visual acuity, reduction of oedema by angiographic methods and use of optical coherence tomography.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
01/05/2004

Eligibility

Key inclusion criteria
Adults with no other ocular pathology apart from diabetic maculopathy sample all are newly diagnosed patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients with ocular pathology apart from diabetic maculopathy

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

St. Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust

Funder Name
Own account

Funder Name
NHS R&D Support Funding

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