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A randomised prospective study to evaluate laser peripheral iridotomy with YAG laser against sequential argon-YAG laser in dark irides

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 12/10/2017	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0141184531

Study information

Scientific Title
A randomised prospective study to evaluate laser peripheral iridotomy with YAG laser against sequential argon-YAG laser in dark irides

Study objectives
To identify the advantages of combined argon-YAG laser iridotomy versus YAG laser alone, in patients of darkly pigmented irides.

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Pigmentation disorders

Interventions
1. Pure YAG laser
2. Argon-YAG Laser

Intervention Type
Procedure/Surgery

Primary outcome measure
Total YAG laser power utilised

Secondary outcome measures

1. Complications (iris haemorrhage, elevated intraocular pressure, intraocular inflammation, focal corneal opacity)
2. Patency of laser iridotomy after single treatment
3. Cost implications of 2 laser treatments versus need for failed iridotomy requiring a second treatment

Overall study start date
23/08/2006

Completion date
22/01/2007

Eligibility

Key inclusion criteria
1. Require iridotomy in both eyes
2. Informed consent available
3. Can follow up after 3 months
4. Dark irides

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Previous failed laser iridotomy
2. History of previous intraocular pathology affecting iris morphology
3. Patients with only 1 functional eye or previous ACG
4. Patients with advanced glaucoma
5. Patients medically unfit for laser treatment

Date of first enrolment
23/08/2006

Date of final enrolment
22/01/2007

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
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
Moorfields Eye Hospital NHS Foundation Trust (UK), 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012		Yes	No