

The impact of indocyanine green (ICG) angiography in multiple diagnostic imaging for the management of exudative age-related macular degeneration (ARMD): a single blind prospective randomised controlled trial of fluorescein angiography vs FA & ICG

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 07/04/2011	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

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Additional identifiers

Protocol serial number

Study information

Scientific Title

Study objectives

Attempt to identify ophthalmic features and positive predictive value for ICG as 'diagnosis and management modifier'. The use of indocyanine green angiography (ICG) may facilitate the identification of lesions that have been proposed to respond to laser treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective randomised controlled trial and pilot study

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Eye Diseases: Age-related macular degeneration (ARMD)

Interventions

Interventions are fluorescein angiography compared with fluorescein angiography and indocyanine green angiography.

Added 05/09/2008: trial was stopped due to new treatments available.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Moderate and severe visual loss defined as loss of three lines or 15 letters (doubling of visual angles) and loss of 6 lines or 30 letters respectively, on a log MAR visual acuity chart, at 4,8 and 12 months.

Key secondary outcome(s)

1. ICG rates modification of fluorescein based diagnosis and management
2. Specificity and sensitivity of ophthalmic signs predictive of ICG findings

Completion date

24/05/2006

Reason abandoned (if study stopped)

New treatments available

Eligibility

Key inclusion criteria

240 patients, of whom 24 are estimated to have retinal angiomatous proliferation (RAP).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

No specific exclusion criteria

Date of first enrolment

24/05/2004

Date of final enrolment

24/05/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Paybody Eye Unit

Coventry

United Kingdom

CV1 4FH

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK), NHS R&D Support Funding

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration