

The effectiveness of early lens extraction with intraocular lens implantation for the treatment of primary angle closure glaucoma

Submission date 22/08/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 23/10/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2017	Condition category Eye 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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Additional identifiers

Protocol serial number

EME 09/800/26 (as of 15/07/2010, previously MRC: G0701604)

Study information

Scientific Title

The effectiveness of early lens extraction with intraocular lens implantation for the treatment of primary angle closure glaucoma: a randomised controlled trial (EAGLE)

Acronym

EAGLE (Effectiveness, in Angle-closure Glaucoma of Lens Extraction)

Study objectives

In patients with primary angle closure glaucoma (PACG), this study will compare the clinical and cost-effectiveness of early lens extraction surgery compared with standard care (usually laser iridotomy followed by a sequence of medical therapy, laser iridoplasty and trabeculectomy).

Ethics approval required

Old ethics approval format

Ethics approval(s)

North of Scotland Research Ethics Committee 2, 09/10/2008, ref: 08/S0802/153

Primary study design

Interventional

Study design

Multinational randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary angle closure glaucoma

Interventions

The participants will be randomly allocate to the following treatments:

Intervention group: Early lens extraction with intraocular lens implantation

Control group: Standard care (usually laser iridotomy followed , as necessary, by a sequence of medical therapy, laser iridoplasty and trabeculectomy)

Total duration of follow-up: 3 years

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Patient-centred outcome: Health Status, assessed by the EQ-5D at 6, 12, and 24 months with the major outcome assessment at 36 months from the date of randomisation
2. Clinical outcome: IOP at 3 year final assessment
3. Economic outcome: Incremental cost per quality adjusted life year (QALY) gained with QALYs based on the responses to the EQ-5D

Key secondary outcome(s)

The following will be assessed at 6, 12, and 24 months with the major outcome assessment at 36 months from the date of randomisation:

1. Patient-centred:
Patient reported, using:

- 1.1. A glaucoma specific utility instrument (GPI)
- 1.2. A vision specific health profile measure (NEI-VFQ25)
2. Clinical:
 - 2.1. Need for trabeculectomy
 - 2.2. Progressive visual field loss
 - 2.3. Best-corrected visual acuity (ETDRS)
 - 2.4. Extension of angle closure (degrees of appositional and synechial angle closure)
 - 2.5. Escalation of therapy
 - 2.6. Number of anti-glaucoma medications
 - 2.7. Intolerance of medications
 - 2.8. Incidence of acute attacks of angle closure
3. Economic:

Costs will be based on resource use data. Costs to the NHS and patients:

 - 3.1. Use of health services for glaucoma related events or treatments
 - 3.2. Patient costs (treatments, spectacles, travel to health services, sick leave)
 - 3.3. Need for alternative management for glaucoma (e.g., surgery, drugs)
 - 3.4. Other use of health services: visits to i) GP, ii) nurse, iii) optometrists

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Both males and females, age ≥ 50 years
2. Diagnosis: either one of the following two types of patients: (i) primary angle-closure glaucoma (PACG), or (ii) primary angle-closure (PAC) with intraocular pressure (IOP) >30 mm Hg
3. Newly diagnosed, i.e. either (i) untreated or (ii) under medical treatment for 6 months or less
4. Angle closure (iridotrabecular contact) in 180 degrees or more
5. Patient must be phakic in the affected eye(s)
6. Written informed consent obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Advanced glaucoma in the potentially eligible eye as determined by either: (i) visual field loss (mean deviation worse than -15 dB) or (ii) cup-disc-ratio >0.9
2. Previously diagnosed acute angle closure attack in the potentially eligible eye
3. Increased surgical risk: e.g., corneal opacity, Fuch's endothelial dystrophy, pseudoexfoliation,

- previous vitreo-retinal surgery, not able to be positioned to undergo standard technique
4. Symptomatic cataract in either eye
 5. Previous cataract surgery or laser iridotomy in study eye
 6. Axial length <19 mm (nanophthalmos)
 7. Secondary angle closure glaucoma
 8. History of retinal ischaemia, macular oedema or wet age-related macular degeneration
 9. Medically unfit for surgery or for completion of the trial

Removed from the protocol as of 04/11/10:

10. Life expectancy <3 years

Date of first enrolment

01/11/2008

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

United Kingdom

Scotland

China

Hong Kong

Malaysia

Singapore

Study participating centre

Aberdeen Royal Infirmary

Aberdeen

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Sponsor information

Organisation

NHS Grampian

Organisation

University of Aberdeen

Organisation

NHS Grampian

ROR

<https://ror.org/00ma0mg56>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	23/05/2011		Yes	No
Results article	results	01/10/2016		Yes	No
	economic evaluation				

Other publications		13/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes