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

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| **Submission date**<br>22/08/2008 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>23/10/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>16/01/2017 | **Condition category**<br>Eye Diseases | |

**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**
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

## Study design
Multinational randomised controlled trial

## Primary study design
Interventional

## 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 -15dB) 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
United Kingdom
AB25 2ZN

## 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<br>economic evaluation | 01/10/2016 | | Yes | No |

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|---|---|---|---|---|---|
| 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 |