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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Augusto Azuara-Blanco

Contact details

The Eye Clinic
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

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 eve(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

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, 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 results	Date created Date added Peer reviewed? Patient-facing?		
Results article		23/05/2011	Yes	No
Results article	results	01/10/2016	Yes	No
Other publications	economic evaluation	13/01/2017	Yes	No

Participant information sheetParticipant information sheet11/11/202511/11/2025NoYesStudy website11/11/202511/11/2025NoYes