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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2008	**Overall study status** Completed	
Last Edited 16/01/2017	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.charttrials.abdn.ac.uk/eagle

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be downloaded from https://viis.abdn.ac.uk/HSRU/eagle/DownloadDefault.aspx

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2008

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

Age group
Senior

Sex
Both

Target number of participants
400 - The trial aims to recruit half of the participants in the UK (n = 200) and the other half in Hong Kong, Malaysia, Singapore and China combined (n = 200).

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
China

Hong Kong

Malaysia

Scotland

Singapore

United Kingdom

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
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Sponsor information

Organisation
NHS Grampian

Sponsor details
Research and Development Office
Foresterhill House Annexe
Foresterhill
Aberdeen
United Kingdom
AB25 2ZB

Sponsor type
Government

Website
http://www.nhsgrampian.org/randd

Organisation
University of Aberdeen

Sponsor details
Polwarth Building
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZD

Sponsor type
University/education

Website
www.abdn.ac.uk

Organisation
NHS Grampian

Sponsor details

Sponsor type
Not defined

Website
http://www.nhsgrampian.org/nhsgrampian/gra_display_home_2015.jsp?p_applic=CCC&p_service=Content.show&pContentID=9298&

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

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	23/05/2011		Yes	No
Results article	results	01/10/2016		Yes	No
Other publications	economic evaluation	13/01/2017		Yes	No