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Foldable versus rigid intraocular lenses in phacoemulsification cataract surgery in Nepal

Submission date	Recruitment status	[ ] Prospectively registered
29/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/02/2011	Eye Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial comparing the effectiveness and cost of foldable and rigid intraocular lenses in phacoemulsification cataract surgery in Nepal

Study objectives
The main aim of the trial is to compare the outcome of foldable and rigid intraocular lenses (IOLs) in phacoemulsification cataract surgery.

There is no significant difference in the visual outcome of phacoemulisfication using either a rigid polymethylacrylate posterior chamber intraocular lens (PMMA PC IOL) or a foldable PC IOL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine (LSHTM) approved on the 22nd July 2010 (ref: 5714)
2. Nepal Netra Jyoti Sangh (NNJS), Institutional Research Review Board, Kathmandu/NEPAL, approved on the 27th August 2010 (ref: 52-067-068)

Study design
Randomised interventional single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cataract surgery (phacoemulsification)

Interventions
In both treatment groups, the cataract will be removed by phacoemulsification, using phaco chop technique (phaco machines: OS-3 OERTLI, Megatron GEUDER). The remaining cortex will be removed with Simcoe cannula and/or bimanual irrigation/aspiration system. In the "foldable" group, the intraocular lens (hydrophilic acrylic, IOCare, India) will be inserted with an injector through the 2.5 mm corneal incision and placed in the capsular bag. In the "rigid" group, the

sclero-corneal incision will be enlarged to 5 mm and a 5 mm optic PMMA IOL (IOCare, India) will be inserted into the capsular bag. The surgery will be performed by two surgeons, both of whom are experienced in using both types of lenses. Treatment is a one-off procedure; follow-up is 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Visual acuity at one year after surgery in the operated eye:
1. Uncorrected visual acuity of 6/9 or more (i.e. very good functional vision)
2. Uncorrected visual acuity of 6/18 or more (i.e. operated eye is no longer "visually impaired" by World Health Organization [WHO] definitions)
3. Best corrected visual acuity worse than 6/60 (i.e. eye is effectively blind)

Secondary outcome measures
1. Visual acuity in the operated eye at other time points
2. Complications during surgery
3. Early post-operative complications
4. Long term complications
5. Astigmatism
6. Cost

Measured at 6 weeks and 12 months.

Overall study start date
25/09/2010

Completion date
24/09/2012

Eligibility

Key inclusion criteria
Patients with cataract, aged 35 to 70 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. Corneal endothelial disease (Fuchs' dystrophy; corneal stromal scarring)
2. Intraocular pressure greater than 22 mmHg
3. A-Scan finding: less than 17.0 dpt, greater than 26.0 dpt
4. Any other eye disease except age related cataract
5. Very advanced hard lens nuclei, where phaco is not suitable (grade III+)
6. Diabetes mellitus

Date of first enrolment
25/09/2010

Date of final enrolment
24/09/2012

Locations

Countries of recruitment
Nepal

Study participating centre
Sagarmatha Choudhary Eye Hospital
Lahan
Nepal
-

Sponsor information

Organisation
Sagarmatha Choudhary Eye Hospital (Nepal)

Sponsor details
G.P.O.Box 15108
Kathmandu
Lahan
Nepal
-

Sponsor type
Hospital/treatment centre

Website
http://www.erec-p.org

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sagarmatha Choudhary Eye Hospital (Nepal)

Funder Name
CBM eV (Germany)

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