

# Foldable versus rigid intraocular lenses in phacoemulsification cataract surgery in Nepal

<b>Submission date</b> 29/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/02/2011	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 phacoemulsification 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, IOLCare, 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

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**Sponsor information****Organisation**

Sagarmatha Choudhary Eye Hospital (Nepal)

**Sponsor details**

G.P.O.Box 15108

Kathmandu

Lahan

Nepal

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**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