

Prospective randomised double masked trial of monofocal, multifocal and accommodative intraocular lens

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/11/2010	Condition category Eye Diseases	☐ Individual participant data

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
N0388119782

Study information

Scientific Title

Study objectives

How effective are accommodating intraocular lens in comparison with monofocal and multifocal lens for patients having undergone cataracts removal?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval for the trial was obtained from the local hospital ethics committee prior to commencement.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract

Interventions

Patients underwent bilateral sequential phacoemulsification with implantation of one of the three IOL types:

1. Accommodative IOL
2. A multifocal IOL
3. A monofocal IOL (control group)

Patients were assessed at 3 and 18 months after second-eye surgery.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/02/2004

Eligibility**Key inclusion criteria**

Patients undergoing cataract surgery who are:

1. Greater than 18 years old
2. Bilateral visually significant cataracts with extraction indicated
3. Informed consent
4. Ability to understand and complete TyPE questionnaire

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Macular or other pathology considered likely to limit post-operative acuity to worse than 6/9 in either eye
2. Corneal astigmatism greater than 1.5 dioptries in either eye
3. Required IOL power outside range available for multifocal IOL (16 - 24 dioptries)

Date of first enrolment

01/02/2003

Date of final enrolment

01/02/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Hillingdon Hospital

Hillingdon

United Kingdom

UB8 3NN

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

The Hillingdon Hospital (UK)

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	01/06/2008		Yes	No