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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 04/11/2010	**Condition category** Eye Diseases	

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.

Study design
Randomised controlled trial

Primary study design
Interventional

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 dioptres in either eye
3. Required IOL power outside range available for multifocal IOL (16 - 24 dioptres)

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