ISRCTN08342378 https://doi.org/10.1186/ISRCTN08342378

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

Contact name
Mr Phillip Bloom

Contact details
The Hillingdon Hospital
Pield Health Road
Hillingdon
United Kingdom
UB8 3NN
+44 (0)1895 238282
phillip.bloom@thh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
69

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
England

United Kingdom

Study participating centre
The Hillingdon Hospital
Hillingdon
United Kingdom
UB8 3NN

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Hillingdon Hospital (UK)

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	01/06/2008		Yes	No