

A prospective randomised controlled trial comparing bilateral multifocal intraocular lens implantation with monovision following cataract surgery

Submission date 12/12/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 29/01/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/04/2015	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

WILM1007

Study information

Scientific Title

A prospective randomised controlled trial comparing bilateral multifocal intraocular lens implantation with monovision following cataract surgery

Study objectives

Null hypothesis:

There is no difference in the percentage of patients that report that they never wear spectacles after bilateral implantation with either TECNIS ZM000 multifocal IntraOcular Lenses (IOLs) or Bausch and Lomb Akreos AO monofocal IOLs with the powers of the monofocal IOLs adjusted to give 1.5 dioptres of monovision.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Moorfields and Whittington Local Research Ethics Committee, 18/10/2006, ref: 06/Q0504/82

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract

Interventions

Bilateral intraocular lens implant with either TECNIS ZM000 multifocal or Bausch and Lomb Akreos AO monofocal intraocular lenses.

Intervention Type

Device

Primary outcome(s)

Percentage of patients with total spectacle independence

Key secondary outcome(s)

1. Visual Function 14-question (VF14) questionnaire
2. Near visual acuity
3. Reading speed
4. Binocular Logarithm of the Minimum Angle of Resolution (LogMAR) acuity
5. Binocular Pelli Robson contrast sensitivity - photopic and dark adapted
6. Procyon pupillometry
7. Forward light scatter - van den Berg forward light scatter test
8. Wavefront aberrations - Shack Hartmann aberrometry

Completion date

01/02/2009

Eligibility

Key inclusion criteria

1. Patients requiring bilateral cataract surgery with good visual potential and a full visual field in each eye
2. Age range 30 to 90 years
3. Biometry indicating IOL power requirement within the range +10 to +30D for emmetropia (0.00 to -0.50D spherical equivalent) in both eyes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients aiming for a refractive result other than bilateral emmetropia (0.00 to -0.50D spherical equivalent) or emmetropia in one eye and low myopia in the other, i.e., the intended monovision outcome
2. Significant co-pathology (including macular pathology, glaucoma, uveitis, corneal disease, diabetic retinopathy, previous retinal detachment surgery)
3. Keratometric astigmatism 1.5D in either eye
4. Amblyopia
5. Congenital or traumatic cataracts
6. Poor comprehension of written or spoken English
7. Inability to give informed consent
8. Mobility, tremor or postural problems causing discomfort during slit lamp examination

Date of first enrolment

01/02/2007

Date of final enrolment

01/02/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR
<https://ror.org/03zaddr67>

Funder(s)

Funder type
Industry

Funder Name
Advanced Medical Optics (AMO) United Kingdom Ltd (UK)

Funder Name
Bausch & Lomb UK Ltd (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	01/12/2013		Yes	No