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

Submission date
12/12/2006

Registration date
29/01/2007

Last Edited
08/04/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
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
WILM1007

Study information

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

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
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 measure

Percentage of patients with total spectacle independence

Secondary outcome measures
1. Visual Function 14-question (VF14) questionnaire
2. Near visual acuity
3. Reading speed
4. Binolcular 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

Overall study start date
01/02/2007

Overall study end date
01/02/2009

Eligibility

Participant 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

Age group
Adult

Sex
Both

Target number of participants
212

Participant exclusion criteria
1. Patients aiming for a refractive result other than bilateral emmetropia (0.00 to -0.50D spherical equivalant) 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

Recruitment start date
01/02/2007

Recruitment end date
01/02/2009

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details
162 City Road
London
England
United Kingdom
EC1V 2PD

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/Home

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

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	01/12/2013		Yes	No