

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 | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/01/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 08/04/2015 | Condition category Eye Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Mark Wilkins

Contact details

Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
United Kingdom
EC1V 2PD
+44 (0)20 7566 2036
mail@markwilkins.co.uk

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 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 dioptries 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

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 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. 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

Overall study start date

01/02/2007

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

Age group

Adult

Sex

Both

Target number of participants

212

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

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 |