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How well does the OriLens (Hubble-type) implant work in improving vision in age-related macular degeneration?

Submission date
02/05/2017

Recruitment status
Stopped

Registration date
24/07/2017

Overall study status
Stopped

Last Edited
01/03/2021

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There are approximately 600,000 individuals in the UK with Age-related Macular Degeneration (AMD), which is a painless condition which causes loss the to an individuals' central vision, causing the vision to become increasingly blurry. AMD exists in two forms 'wet' (neovascular) or 'dry' (atrophic), with new treatments becoming available for the 'wet' form of AMD, however, no treatment exists for the 'dry' form of AMD or those who do not respond to existing treatments. A novel treatment in AMD patients has been the use of intraocular telescopes, a magnifying lens which is implanted into the eye; this can be done at the time of cataract surgery or as a separate surgery. These intraocular telescopes provide high magnification for distance viewing while still allowing near vision tasks, such as reading, to be carried out as normal through reading glasses (if required). This study will use a novel intraocular telescope called OriLens, which uses mirrors resulting in an implant which is smaller than other intraocular telescopes currently available. The smaller size of the OriLens offers the potential for an easier surgery and a faster recovery time. The aim of this study is to evaluate the efficacy and safety of the OriLens to improve vision for those with severe AMD.

Who can participate?
Adults aged 55 to 100 who have AMD requiring treatment.

What does the study involve?
Potential participants are screened in order to make sure they are suitable for the study. They then have laster treatment in the selected eye (if they have already had this done prior this procedure is not repeated). Participants are then allocated to one of two groups. Those in the first group receive the surgery where the telescope lens is inserted. They are also tested for new glasses are provided with appropriate spectacles and low vision aids. They also receive three sessions of Low Vision Training. Those in the second group receive the three sessions of low vision training and are tested for new glasses, receiving appropriate glasses and low vision aids. All participants are asked to attend four follow up appointments where they undergo eye tests and training. They are also asked about their health and vision related quality of life. Those in the first group receive two additional appointments following their surgery.

What are the possible benefits and risks of participating?
While there is no guarantee that participants will benefit from taking part in the study, the potential benefits to participants include additional low vision training. Half of the participants taking part in the study will receive the intraocular telescope, and may benefit from magnified central vision as a result. Those receiving the intraocular telescope will require surgery to insert this, which may involve some risk. As with any surgery the main risk is infection, and in order to reduce the risk of infection antibiotics will be placed in the eye at the time of surgery and participants will be required to use eye drops for a month after the surgery. Some mild discomfort and redness in the eye is to be expected following the surgery, with eye usually being comfortable within 48 hours of the procedure, and it is expected that the eye will have healed within one month.

Where is the study run from?
This study takes at the Belfast Health and Social Care Trust (Lead Centre) and nine other sites in the UK.

When is the study starting and how long is it expected to run for?
September 2015 to February 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Catherine Adams
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2016-000887-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33480

Study information

Scientific Title
Efficacy of the Telescopic Mirror Implant for Age-related Macular Degeneration: The MIRROR Trial

Acronym
MIRROR

Study objectives
The aim of this study is to evaluate the efficacy and safety of a new intraocular implantable device (OriLens) to improve vision in participants with severe Age-related Macular Degeneration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands- Nottingham 1 Research Ethics Committee, 23/05/2016, ref: 16/EM/0212

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Ophthalmology, Primary sub-specialty: Retina (including Diabetes); UKCRC code/ Disease: Eye/ Disorders of choroid and retina

Interventions

The study is conducted for those who have Age-related Macular Degeneration (AMD) and have had cataract surgery in both eyes. Before entering the study potential participants aree screened at two appointments to make sure they meet the needs of the study. Once a participant has been selected they have laser treatment in the selected eye (if a participant has already had the laser treatment they will not have to have the procedure repeated). The planned interventions are posterior Nd:YAG capsulotomy in the study eye (if not already done) for all eligible participants. Participants are randomised (stratified by site) after Nd:YAG capsulotomy (if required) to one of two groups:

Group 1: Surgical implantation of the OriLens device plus three sessions of low vision training

Group 2: Three sessions of optimised low vision training with the opportunity to try external telescopes for day-to-day tasks. In order to minimise the possibility of a placebo effect, an equal number of low vision sessions are given in each Group. Participants are required to attend four appointments over the course of a year, in order to monitor any changes to their vision during this period.

Appointments are arranged one month, three months, six months and 12 months following randomisation for both groups. Individuals randomised to the intervention group (Group 1) attend two additional post-operative appointments, one day and one week following surgery. Medical history, ophthalmic examination, visual acuity tests and inquiries into adverse events are conducted at each appointment. Visual rehabilitation training take place for all participants are months one, three and 12. Questionnaires to assess health service use and health and vision related quality of life are administered at months six and 12. On the final appointment (month 12) fundus photography and specular microscopy are also be performed.

Intervention Type
Other

Primary outcome measure
BCDVA is measured using number of letters improvement on ETDRS Chart at baseline and 12 months.

Secondary outcome measures
1. BCDVA is measured using number of letters improvement on ETDRS Chart at one, three and six months
2. BCNVA, reading speed and contrast sensitivity is measured by MNRead Chart and MARS Chart at baseline and 12 months
3. Vision-specific quality of life measured using the IVI at baseline, six and 12 months
4. Health related quality of life status is measured using the EQ-5D-5L questionnaire at baseline, six and 12 months
5. Health service use and associated costs are measured by a Health Service Use Questionnaire at six and 12 months

Overall study start date
01/09/2015

Completion date
28/02/2019

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged between 55 and 100 years (both male and female)
2. Bilateral stable advanced AMD either neovascular (required to be stable for at least 12 months after last treatment) or atrophic AMD
3. Bilateral uncomplicated cataract surgery with unifocal intraocular lens positioned within the capsular bag
4. Bilateral best-corrected distance visual acuity of 6/38-6/240 (LogMAR 0.80 to 1.60)
5. Must demonstrate a 10-letter improvement in BCDVA (ETDRS chart) with the external x2.5 telescope in the eye for implantation
6. Must have had experience of using low vision aids
7. Must have an anterior chamber depth (ACD) of ≥3mm in both eyes
8. Must have a pupil size ≥3mm in diameter in both eyes
9. Must have an endothelial cell density within normal limits for age (see appendix 1)
10. Must be willing to undergo laser capsulotomy in the eligible eye prior to randomisation (if not already done)
11. Must be three months or more following any intraocular surgical procedure and one month following YAG capsulotomy
12. Must be in good general health with every likelihood of involvement in the trial for the duration of the study and be able to physically or verbally complete the questionnaires

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 132; UK Sample Size: 132

Key exclusion criteria
1. Cataract surgery with multifocal intraocular lenses
2. A history of glaucoma or of being on anti-glaucomatous medication
3. Any other retinal condition
4. Lack of clear view of the retina
5. Abnormal or de-centred pupil
6. Endothelial cell density <1500 cells/mm2
7. History of ocular inflammatory disease
8. Zonular instability or instability of existing intraocular lens
9. BCDVA of better than 6/38 (0.80 LogMAR) or worse than 6/240 (1.60 LogMAR) in either eye
10. Participants unable to provide informed consent
11. Be in poor general health that could compromise attending follow-up assessments
12. Difficulties with balance
13. Not fluent in English

Date of first enrolment
23/05/2017

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Belfast Health and Social Care Trust (Lead Centre)
Eye & Ear Clinic
The Royal Hospitals
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
St. James's University Hospital
Eye Clinic
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Liverpool University Hospital
St Paul's Eye Unit
Liverpool
United Kingdom
L7 8XP

Study participating centre
Moorfields Eye Hospital
162 City Road
London

United Kingdom
EC1V 2PD

Study participating centre
St. Thomas Hospital
Department of Ophthalmology
Lambeth Palace Road
London
United Kingdom
SE1 7EH

Study participating centre
University Hospital Aintree
Ophthalmology Department
Longmoor Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
James Cook University Hospital
Eye Outpatients
Marton Road
Middlesborough
United Kingdom
TS4 3BW

Study participating centre
Southampton General Hospital
Eye Unit
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Sunderland Eye Infirmary
Research Office
Queen Alexandra Road

Sunderland
United Kingdom
SR2 9HP

Sponsor information

Organisation
Belfast Health & Social Care Trust

Sponsor details
Knockbracken Healthcare Park
Saintfield Road
Belfast
Northern Ireland
United Kingdom
BT8 8BH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is planned that the study findings will be published in national and international peer review journals which will be led by the CI, approximately one year after the trial ends.

Intention to publish date
28/02/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4	14/12/2016	25/10/2017	No	Yes
HRA research summary			28/06/2023	No	No