

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/07/2017	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/03/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 laser 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

CatherineX.Adams@nictu.hscni.net

Contact information

Type(s)

Public

Contact name

Dr Catherine Adams

Contact details

Northern Ireland Clinical Trials Unit

1st Floor Elliott Dynes Building

The Royal Hospitals

Grosvenor Road

Belfast

United Kingdom

BT12 6BA

+44 28 90635794

CatherineX.Adams@nictu.hscni.net

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 are 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 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 ≥ 3 mm in both eyes
8. Must have a pupil size ≥ 3 mm 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
Middlesbrough
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