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Implant two piece intra-ocular lens system for treating dry age-related macular degeneration

Submission date
12/11/2012

Recruitment status
No longer recruiting

Registration date
16/11/2012

Overall study status
Completed

Last Edited
06/04/2016

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Age-related macular degeneration (ARMD) is an eye condition that causes loss of central vision, usually in both eyes. There are two main types: dry ARMD and wet ARMD. Dry ARMD develops when the part of the eye responsible for central vision (the macula) is damaged by a build-up of deposits and is unable to function as effectively. There has been a recent renewal in interest in treating ARMD with lens implantation, where the lens of the eye is removed and replaced with an artificial lens designed to improve central vision. In recent years Soleko has developed the IOL VIP intraocular lens that in combination with a rehabilitation program has improved vision in ARMD patients. See Again Europe has designed an intraocular lens to improve the vision of ARMD patients who have remaining healthy macula. From a clinical perspective the procedure to implant the See Again Lens is equivalent to that of the IOL VIP device but with the potential advantage of focusing the image on the healthier area of the macula. The aim of this study is to evaluate the performance of the See Again Lens device to improve vision in patients with dry ARMD.

Who can participate?
Patients with significant stable dry ARMD

What does the study involve?
The eye's natural lens is replaced with a two-lens system that magnifies and diverts the image to a healthy part of the macula. The implantation procedure is performed under local anaesthetic and is expected to take 45 minutes. Eye tests are carried out within 24 hours of the implantation procedure and 2, 4, 8 and 12 weeks and 3 months later.

What are the possible benefits and risks of participating?
It is anticipated that patients' vision will improve and achieve a two-line improvement as judged by standard eye test charts. The procedure is similar to a cataract operation and has the same risks as this routinely performed implantation.

Where is the study run from?
The study will be conducted locally as convenient for the patient. It will be performed in clinical facilities approved for eye surgery by the Care Quality Commission.

When is the study starting and how long is it expected to run for?
January 2013 to January 2017

Who is funding the study?
See Again Europe Ltd (UK)

Who is the main contact?
CEO, Steve Jennings
steve@seeagain.co.uk

Contact information

Type(s)
Scientific

Contact name
Mr Brendan Moriarty

Contact details
The Prospect Eye Clinic
Market Street
Altrincham
United Kingdom
WA14 1PF
-
deryn@brendanmoriarty.com

Additional identifiers

Protocol serial number
See Again 100 001

Study information

Scientific Title
Double intra-ocular lens implant for visual rehabilitation of patients with dry age-related macular degeneration

Acronym
MDSAT1

Study objectives
The study will evaluate the performance of the See Again Lens device, using an established surgical procedure, to improve vision in patients with macular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design
Interventional

Study design
Proof of concept trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Age-related macular degeneration

Interventions
Patient suitability:
An ocular examination to determine patients suitability for the See Again assessment, usually 30 minutes duration.
Confirmation from patients GP that there is no reason why the patient should not be part of the trial.

Patient assessment:
An ocular assessment using the See Again lens set that predicts the visual acuity improvement of the implant procedure, usually 15 minutes duration.

Independent assessment:
An independent ocular assessment of the patient before the implant procedure is performed, usually 1 hour duration.

Pre operation assessment:
An ocular examination performed immediately prior to performing the implant procedure, expected to take 15 minutes.

Implant the lens system:
Perform the implant procedure of the See Again lens system under local anesthetic, expected to take 45 minutes.

Post operation assessment:
Initial ocular examination within 24 hrs of the implant procedure being performed, expected to take 15 minutes.

2 weeks post operation assessment:
Ocular examination 2 weeks post performing the implant procedure, expected to take 30 minutes.

4 weeks post operation assessment:
Ocular examination 4 weeks post performing the implant procedure, expected to take 30 minutes.

8 weeks post operation assessment:
Ocular examination 8 weeks post performing the implant procedure, expected to take 30 minutes.

12 weeks post operation assessment:
Ocular examination 12 weeks post performing the implant to determine that vision has stabilised, expected to take 30 minutes.

Independent post operation assessment:
Independent visual acuity test to be performed after 3 months, usually 1 hour duration.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. An improvement from baseline in the patients final best corrected visual acuity (using ETDRS Chart). An improvement of 2 lines or more will constitute a positive result for a patient.
2. Mean or median improvement values will also be analysed at 3 months.

The measures of the independent assessor will be employed.

Key secondary outcome(s)
The proof of concept secondary outcome measures are
1. Endothelial cell count will be compared to the patients baseline. A deterioration of less than 20% will constitute a positive result.
2. Improved mobility of the patient, this will be subjective based on patient response. Any perceived improvement in mobility will constitute a positive result.
3. Improved wellbeing of the patient, this will be subjective based on patient response to navigational capability and dependence on relatives and/or carers. Any perceived improvement in wellbeing will constitute a positive result.

If successful, much larger trials will be undertaken in Ireland, UK and France that will define the predictability and reproducibility of performing the implant procedure.The health economics case will be collected from the same group of patients over a longer period (2 years) and will be based based on changes to direct healthcare costs, indirect healthcare costs and care costs in the community.

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. The ophthalmic surgeon will select suitable patients
2. Patients with significant stable macular degeneration (dry), ideally with less than two disc diameters of ARMD
3. Patients must have significant lens opacities in the affected eye and a visual acuity of <6/36
4. Patients must have an endothelial cell count greater than 1,600 per square mm in the affected eye
5. Patients must demonstrate a positive screening test result when using the the See Again assessment lens set i.e. exhibit at least a two line improvement when reading the ETDRS Chart

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with active ARMD
2. Patients with active ocular inflammation
3. Patients with previous cataract surgery
4. Patients with lack of mental capability to give informed consent
5. Patients with an inability to understand spoken and written English
6. Patients who are involved or have been involved in a research study

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Prospect Eye Clinic
Altrincham
United Kingdom
WA14 1PF

Sponsor information

Organisation
See Again Europe Ltd (UK)

Funder(s)

Funder type
Industry

Funder Name
See Again Europe Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration