ISRCTN15358662 https://doi.org/10.1186/ISRCTN15358662

Validation of the SightSave vision test

Submission date 31/12/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/02/2023	**Overall study status** Completed	
Last Edited 30/10/2023	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and aims
We are aiming to compare the SightSave contrast sensitivity app that is performed on a touchscreen device with standard chart-based contrast sensitivity analysis. This will help determine if the SightSave contrast sensitivity app can be used at home by eye patients to check their eyesight.

Who can participate?
Individuals with cataracts who are due for standard cataract surgery with intraocular lens implant procedures.

What does the study involve?
Participants will have their vision tested using a range of 4m LogMAR contrast sensitivity charts and these results compared to the SightSave contrast sensitivity analyser at the same levels of contrast to validate the SightSave contrast sensitivity analyser pre and post cataract surgery to see if there is a comparable contrast sensitivity before and after surgery and if any improvements are recorded by the tests.

What are the possible benefits and risks of participating?
The benefits of participating in the study are that your vision will be very accurately measured before and after your surgery, the risks are that you are made aware of your poor vision, which might be upsetting.

Where is the study run from?
Edgbaston Eye Consultants (UK)

When is the study starting and how long is it expected to run for?
December 2022 to December 2023

Who is funding the study?
ScottHealth Ltd (UK)

Who is the main contact?
Prof. Robert AH Scott, rob.scott@scotthealth.co.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Robert Scott

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
324467

Protocol serial number
Nil known

Study information

Scientific Title
Validation of the SightSave contrast sensitivity application against standard logMAR constrast sensitivity charts

Acronym
VASCA

Study objectives
The SightSave contrast sensitivity app generates similar measurements to standard contrast sensitivity chart testing

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approval pending, West Midlands – South Birmingham REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8143; southbirmingham.rec@hra.nhs.uk)

Study design
Method-comparison study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Testing of contrast sensitivity

Interventions
Subjects will have their visual acuity measured using 4m logMAR visual acuity charts at contrast levels 1.25%, 2.5%, 5% ,10%, 25% and 100% and then use the SightSave contrast sensitivity app on a touchscreen device - all under standard conditions

Intervention Type
Other

Primary outcome(s)
LogMAR visual acuity at contrast levels 1.25%, 2.5%, 5%,10%, 25% and 100% measured using 4m logMAR visual acuity charts and the SightSave contrast sensitivity app on a touchscreen device

Key secondary outcome(s))
At the end of the testing:
1. Time taken to complete each test
2. 5 point scale evaluation by the patient of the ease of testing for them

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Has visually significant cataract and listed for a cataract surgery with intraocular lens implant procedure
2. Patient consents to having contrast sensitivity testing on SightSave contrast sensitivity app and logMAR contrast sensitivity charts
3. Patient is able to use the logMAR charts and has capacity to read the letters

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to use either or both, logMAR contrast sensitivity chart
2. Unable to read the chart letters

Date of first enrolment
01/04/2023

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Edgbaston Eye Consultants
22 George Road
Birmingham
United Kingdom
B15 2NE

Sponsor information

Organisation
ScottHealth Ltd

Funder(s)

Funder type
Industry

Funder Name
ScottHealth Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Robert AH Scott rob.scott@scotthealth.co.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			27/01/2023	No	No