

Validation of the SightSave vision test

| | | |
|--|---|--|
| Submission date 31/12/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 07/02/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 30/10/2023 | 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 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

ORCID ID

<https://orcid.org/0000-0003-3437-5698>

Contact details

Edgbaston Eye Consultants
22 George Road
Birmingham
United Kingdom
B15 1PJ
+44 1213144490
rob.scott@scotthealth.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

324467

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Validation of the SightSave contrast sensitivity application against standard logMAR contrast 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 |