OCCUTRACK

CRYSTALSIGHT: Clinical Evaluation of OCCUTRACK's CRYSTALSIGHT Device through Remote Monitoring for Disease Recurrence of Wet AMD **(Cohort 2.0)**

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Study Summary

Age-Related Macular Degeneration (AMD) and Diabetic macular Edema (DME) is one of the main causes of central vision loss. Most patients require pharmacologic treatment with anti-vascular endothelial growth factor (VEGF) agents with multiple follow-up visits that include optical coherence tomography (OCT), visual acuity testing and multiple injections.

The high frequency of visits puts pressure on eye clinics and can be extremely stressful for both patients and their caregivers. Therefore, portable and rapidly deployable self-administered home-based examination devices are key to making telemedicine a reality.

OCCUTRACK Medical Solutions has developed a portable, self-administered device designed for gaze-tracking and monitoring of patients with retinal diseases such as

AMD and DME, and choroidal neovascularization (CNV) that require multiple anti-VEGF injections.

The team have confirmed the performance of the CRYSTALSIGHT device and validated the retinal thickness measurements obtained with this device by comparing it to in-hospital Optical Coherence Tomography (OCT) (Heidelberg Spectralis). In this study, the team will conduct a randomized clinical trial RCT to compare the efficacy and cost-effectiveness of a Pro Re Nana (PRN) management regimen enhanced with the CRYSTALSIGHT home monitoring device for the detection of central metamorphopsia with existing PRN standard of care for patients with AMD or DME exiting the anti-VEGF injection regimen.

Study Objectives

Primary Objective:

To demonstrate that the home monitoring of a PRN regimen with the CRYSTALSIGHT telemonitoring system is non-inferior to the Amsler grid[1] in detecting recurrence of wet AMD based on central retinal thickness (CRT) increase of at least 50 microns or a loss of best-corrected visual acuity (BCVA) of 5 letters or more.

Detection of using visual field test gaze tracking results in earlier detection of AMD/DME associated with (CNV), as reflected by better visual acuity compared with standard care. Outcome of this trial is to determine the sensitivity and specificity of CRYSTALSIGHT with reactivation subtle neovascular age-related macular degeneration that was detected by the regular use of a home monitoring device based on gaze-based preferential hyperacuity visual field testing.

An important predictor of the benefit of treatment with anti-vascular endothelial growth factor (VEGF) agents is visual acuity at the time of CNV treatment.

Secondary Objectives

1. Correlate CRYSTALSIGHT scores with BCVA and OCT findings.
2. Identify diagnostic performance of CRYSTALSIGHT (ROC, AUC).
3. Develop risk scoring algorithms for wet AMD recurrence.

Background work

For patients who have lost vision in one eye due to wet age-related macular degeneration (wAMD), preservation of functional visual acuity in the other eye is of paramount importance. However, clinical experience and research have shown that these and other high-risk patients often fail to use the Amsler grid between clinic visits to detect the earliest signs of neovascularization in their good eye.

Normal human vision consists of a series of rapid eye movements called saccades that abruptly change the fixation point depending on the area of the person's eye. OCCUTRACK's CRYSTALSIGHT device tracks these eye movements with generated

patterns on the screen, a visual assessment of affected and unaffected eyes is achieved without expensive optics and at home on any tablet or laptop computer.

CRYSTALSIGHT is a home-based gaze-tracking readily available for home hyperacuity monitoring for these and other high-risk eyes with diagnosed wet-AMD.

The Device

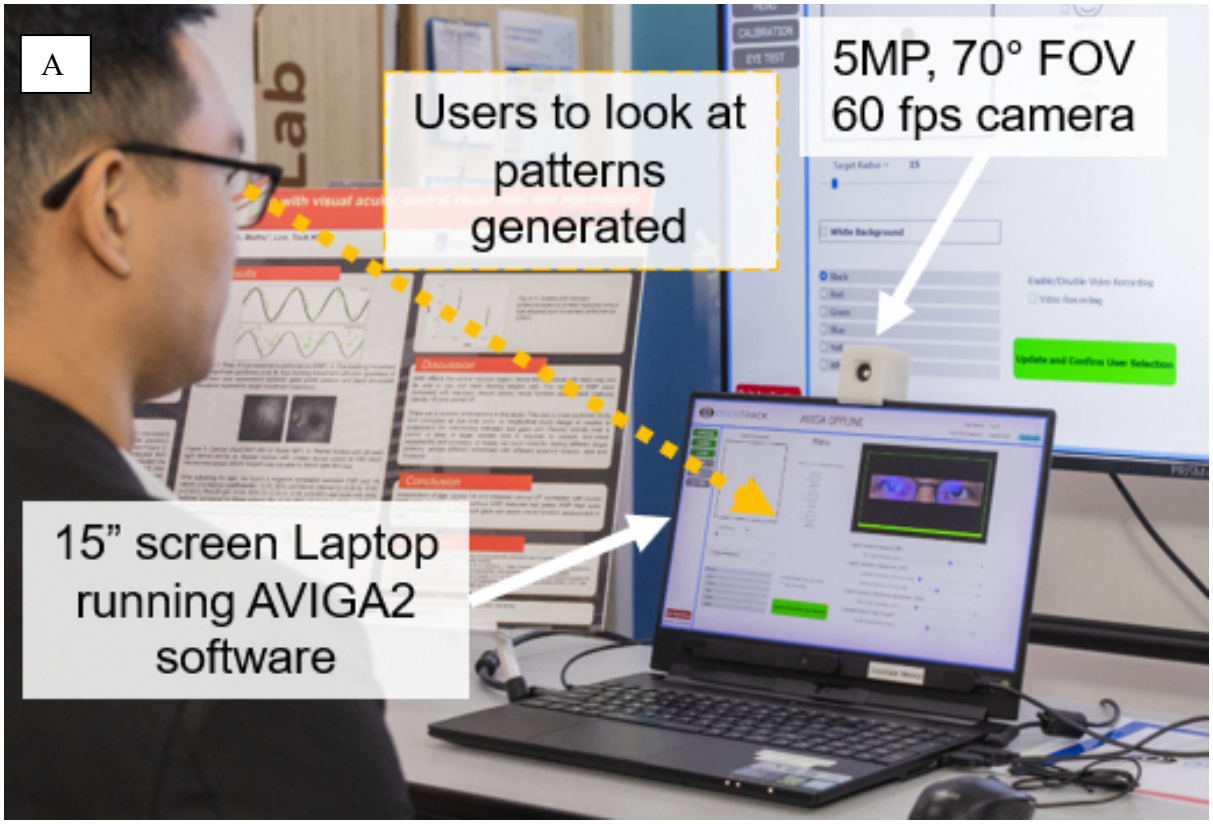

Figure 1 CRYSTALSIGHT device being used in a home-based setting.

The system consists of a gaze-based hyperacuity perimetry device that requires no physical interaction, the software generates proprietary metamorphopsia detection algorithms, and the specific telemonitoring protocols that are followed at a prescribing trial centre. Occutrack supplies the devices to patients who have received a prescription from an ophthalmologist.

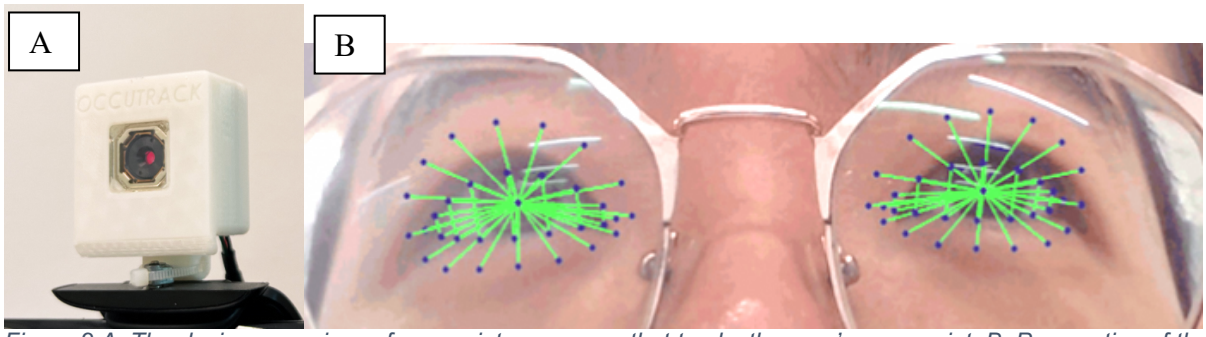

Figure 2 A: The device comprises of a proprietary camera that tracks the user's gaze point. B: Perspective of the camera with machine vision augmentation.

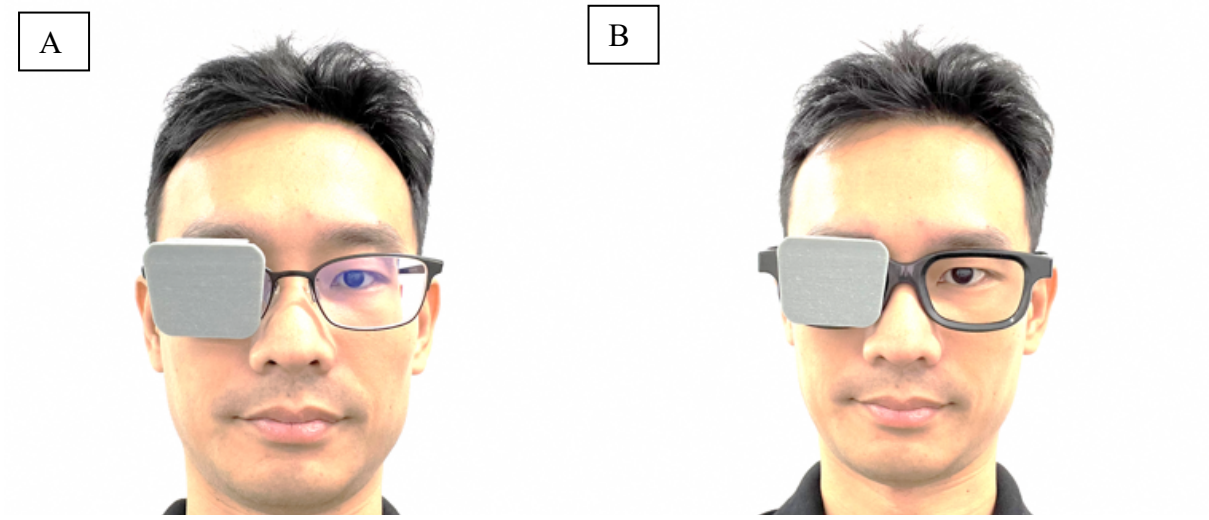

Figure 3 Participants in the study will be provided with a monocular occluder that is attached to A: corrective prescription frames (a) or a B: lensless frame, gaze-tracking accuracy is unaffected by lenses.

When an wAMD patient takes a test done twice weekly — the results are transmitted electronically to the clinical trial site. If the algorithm detects suspicious results, a digital flag is raised and a manual comparison to the patient's baseline is reviewed by the principal investigator (PI).

As for test results, the location and size of metamorphopsias and scotomas are inferred from the patient's reaction patterns to a series of generated dot patterns that the CRYSTALSIGHT device flashes at various points in the visual field. Some dots appear, move and disappear pseudo-randomly on the screen, the patient simply needs to look at the screen.

The purpose of this clinical validation study is to demonstrate that the CRYSTALSIGHT automated vision screening device is suitable for use at home twice a week to detect the recurrence of wet AMD in all ethnic groups.

Compared with the patient's baseline tests, erroneous or absent clicks indicate metamorphopsia, which could be due to early choroidal neovascularization (CNV). The threshold for a positive test for each parameter before this study start is determined by the on-going cohort-1 clinical study in progress.

Patients are automatically reminded if they fail to test themselves regularly. The treating ophthalmologist receives monthly longitudinal reports and immediate

notification of abnormal readings so that an examination can be scheduled immediately.

The patterns of the dots are described as follows:

Static Fixation Evaluation (SFE)	Static Perimetry Assessment (SPA)	Static Perimetry Sensitivity Assessment (SPSA)	Pursuit
Visual Field fixation	Saccadic visual field	Saccadic Visual Field Sensitivity	Ocular motility
A single large discrete target is displayed filling the entirety of the screen and shrinks to 10pixels for 5 seconds. The target is presented twice. The user under test's fixation radius is scored as a Circular-Error Probable (CEP) size. The smaller the CEP radius, the better the test result.	A set of 13 discrete targets are displayed randomly and twice repeatedly on fixed coordinates for a preset duration of 1 second (adjustable) on the screen for the user under test. Targets are presented in a pseudo-randomly to avoid bias in gaze point detection. An area-of-effect radius is scored if the user's gaze intersects with the presented target.	A set of 13 discrete targets that increases in radius at 10 pixels/second are displayed randomly on fixed coordinates on the screen for the user under test. Targets are presented in a pseudo-randomly to avoid bias in gaze point detection. The target radius is scored if the user's gaze intersects with the presented target at the presented radius size. The smaller the radius, the better the test result.	Subject under test to pursue a generated target moving in a sinusoidal pattern at a speed of 5cm/s.

Methodology

This study aims to determine whether home-based monitoring using the CRYSTALSIGHT gaze-based Hyperacuity Perimetry system, when added to a PRN treatment regimen, is non-inferior to standard care using the Amsler Grid in detecting recurrence of choroidal neovascularisation (CNV) associated with wet age-related macular degeneration (AMD).

Recurrence is defined by a central retinal thickness (CRT) increase of ≥50 microns or a loss of best-corrected visual acuity (BCVA) of ≥5 letters.

The study also aims to evaluate whether CRYSTALSIGHT enables earlier detection of CNV progression, as reflected by better VA and CRT values at the time of detection, through biweekly self-tests conducted in an unsupervised home setting.

Study Design

This is a randomised, open-label, non-inferiority clinical trial comparing two parallel arms: a standard care arm using Amsler Grid home monitoring (PRN), and an intervention arm using the CRYSTALSIGHT gaze-tracking system (PRN+). A total of 220 (Singapore – 60, United Kingdom – 80, United States – 80) participants will be randomised in a 1:1 ratio. Participants in the intervention arm will self-administer biweekly CRYSTALSIGHT tests at home, while those in the control arm will use the Amsler Grid. Both arms will attend monthly clinic visits for standard evaluations, including VA, BCVA, and OCT. Alerts generated by the CRYSTALSIGHT system based on deviation thresholds will trigger early clinic recall for confirmatory imaging and potential re-treatment.

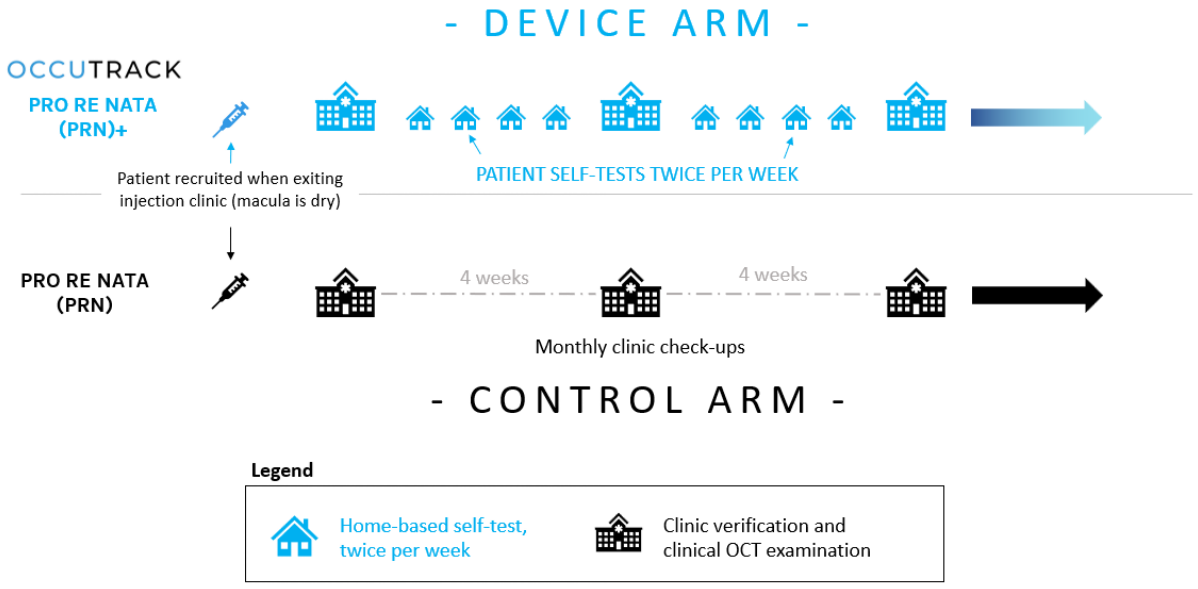

Figure 4 Details of the home-use clinical trial study design. The trial objective: show that PRN+ is non-inferior to standard of care PRN with better VA/VF outcomes

Development of CRYSTALSIGHT cutoff scores should have been conducted in the cohort-1 1 study [NCT: NCT06518512] (Analysis). This Phase 2 should be the application of validated cut-off scores. The second aim will be to compare the accuracy of CRYSTALSIGHT and Amsler, and sensitivity and specificity check.

In addition to identifying CRYSTALSIGHT visual risk prediction cut-off scores, detection yields, and diagnostic Performance indicators will also be evaluated. Progression to CNV was

determined by the investigator, based on standardised OCT confirmation. At the clinical trial site, these events were confirmed by gradings conducted by masked, certified independent personnel who did not know the treatment assignment. Events from both arms are graded using a standardised protocol.

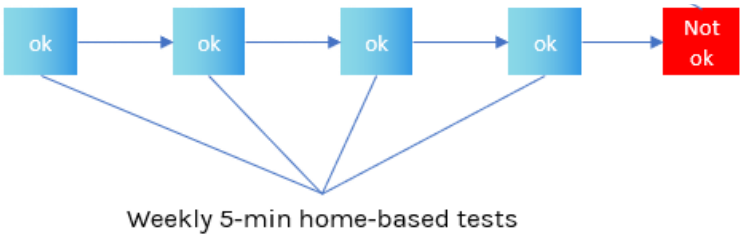

Figure 5 In Cohort 2, home-based score deviation detected, study coordinator will schedule hospital checkup immediately. If CRYSTALSIGHT correctly detects wet AMD recurrence confirmed by OCT, subject exits the study.

This study will use the CRYSTALSIGHT system in an unsupervised home setting. Participants will perform biweekly self-monitoring with the CRYSTALSIGHT device. The threshold algorithm will be implemented and validated with subjects. Threshold information from Cohort 1 will thus be incorporated into the Cohort 2 intervention measures. Figure 5 illustrates the function of the CRYSTALSIGHT score as the basis for an intervention measure: an earlier-than-expected clinic visit should be scheduled immediately for clinic vision testing and urgent anti-VEGF administration.

Pro Re Nata (PRN): Standard treatment (control arm)

Participants randomized to the standard treatment arm received specific instructions from investigators for self-monitoring of vision at home to detect progression of AMD. Aids such as the Amsler grid. This group is referred to below as the standard treatment group. If participants experienced symptoms, they were instructed to call their clinical centre immediately and schedule an appointment within 72 hours.

PRN+: Home monitoring device (device arm)

In addition to the same standard of care instructions, participants will receive a CRYSTALSIGHT home monitoring device with instructions for installation and use. This arm is referred to below as the device arm. In cases where baseline measurements could not be obtained due to a pre-existing visual field defect in at least one study eye, participants returned the device and continued monitoring with standard treatment only but were still included in the final analyzes in the intent-to-treat (ITT) cohort as part of the device arm.

Participants were encouraged to use the device twice a week, and results were automatically transmitted via internet cloud to a Occutrack's data monitoring center. If testing of the device indicated a change from baseline measurements, an alert was sent from the monitoring center to the participant's clinical center, prompting staff to schedule an appointment with the study ophthalmologist within 72 hours.

This study is an open-label, randomized study designed to evaluate the safety and efficacy of the CRYSTALSIGHT device when used by patients in their own homes. The study will

recruit a group of patients who meet certain eligibility criteria and provide them with the CRYSTALSIGHT device for use at home.

The Cohort 2 study typically several phases, including a screening phase to identify eligible patients who could be recruited patients exiting the anti-VEGF injection clinic. The phases are:

- **Training**: a training phase for the device to ensure that patients know how to use the device properly, a testing phase in which patients use the device to monitor their vision condition using the CRYSTALSIGHT device over a period of time until the device detects deterioration in vision and meets the criteria for deterioration established by the Cohort 1 results, and a follow-up phase to assess results and obtain feedback from patients.
- **Monitoring**: During the study, patients will be asked to follow the specific protocols and guidelines for use of the CRYSTALSIGHT device, such as completing the bi-weekly regular testing. Patients will also be asked to report or provide feedback on any adverse events or problems encountered while using the device.
- **Intervention**: Should the CRYSTALSIGHT device determine that a threshold for vision deterioration has been reached (delta deviation of 10 points from the nominal baseline), the patient/participant will receive a notification from the prescribing physician and the electronic alert system via email to the subject's personal mobile device instructing them to schedule an appointment for confirmation OCT -A that the subject's wet AMD has recurred, see Figure 6 below.

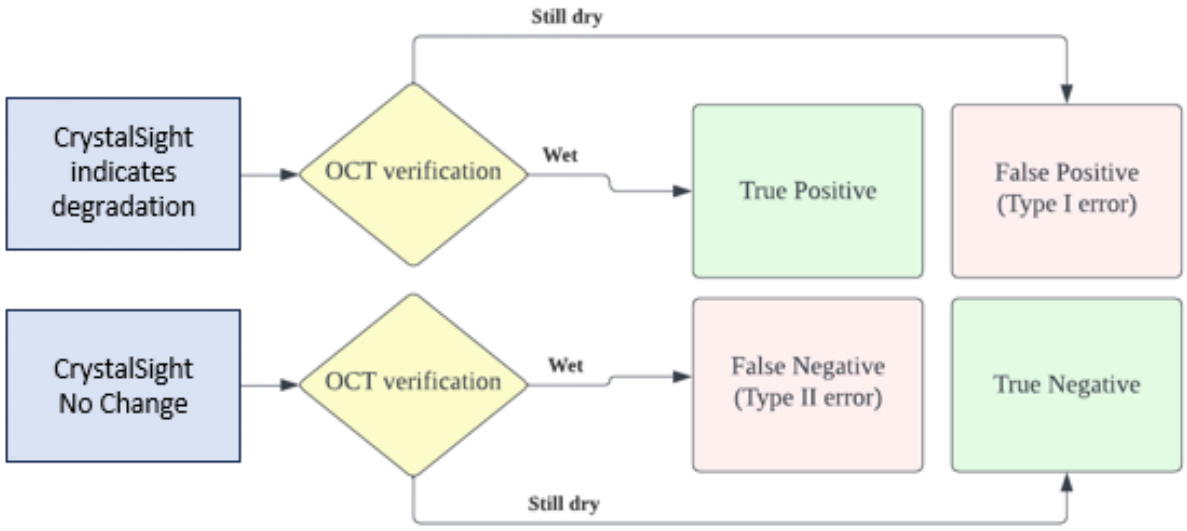

Figure 6 True-False confusion matrix of cohort-2 will require OCT confirmation of wet AMD disease recurrence that was detected by CRYSTALSIGHT.

This cohort 2 intervention study is designed to collect data on the safety and efficacy of the device, including information on the accuracy, reliability, and ease of use of the device. The study may also examine the impact of the device on patient outcomes, such as changes in visual status or quality of life.

Once the study is complete, the data will be analyzed to determine if the device is safe and effective for home use. If the results are positive, the device can be submitted to the FDA for approval and made available to patients who need it.

Cohort-2 study relationship to the cohort-1

The CRYSTALSIGHT eye tracking system is a medical monitoring system used to treat age-related macular degeneration (AMD). AMD is a disease that affects the macula, the part of the eye responsible for central vision. CRYSTALSIGHT helps people with AMD maintain their quality of life by improving their ability to perform everyday activities.

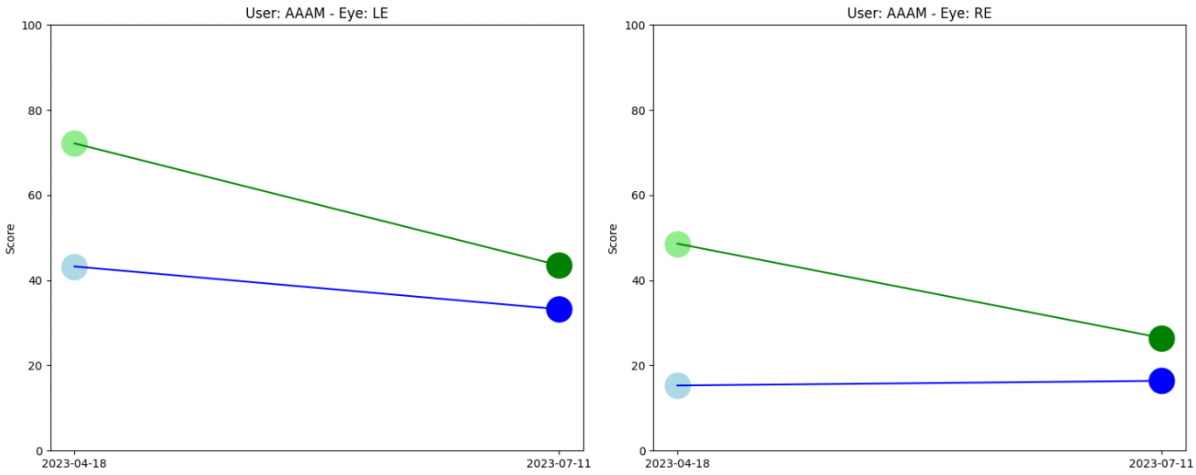

Figure 7 Cohort 1 results of a single test subject showing the correlation of OCT scores to CRYSTALSIGHT at two clinic visits.

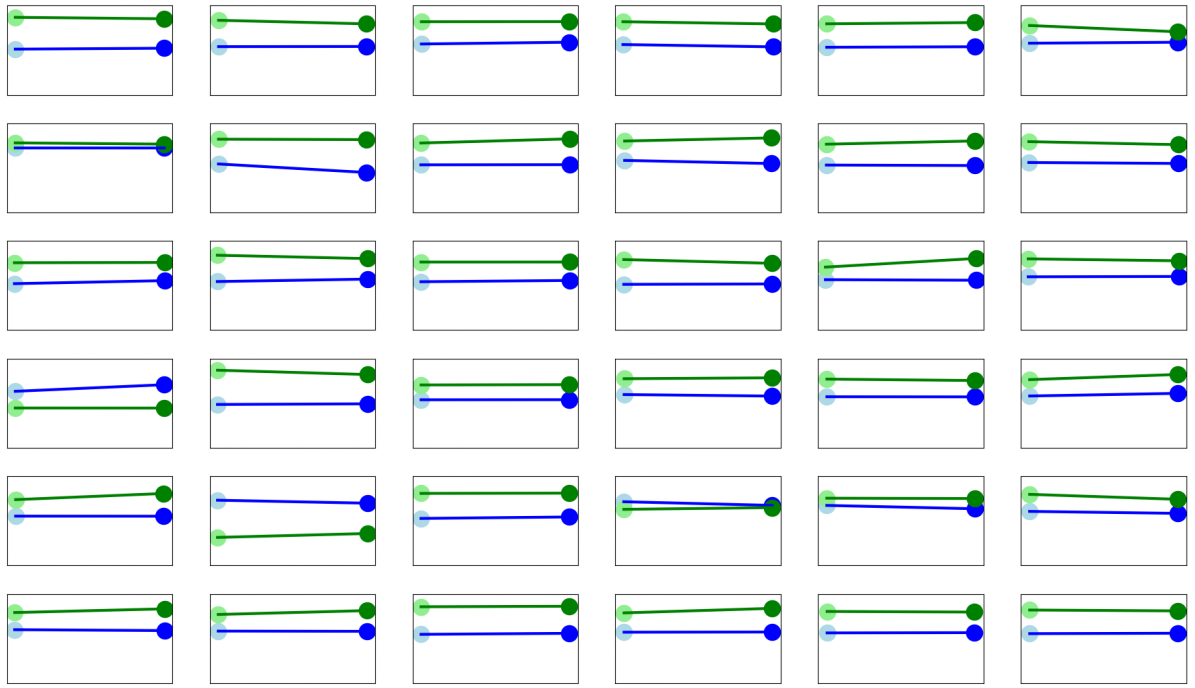

Figure 8 Population of cohort-1 study, each box represents a tested eye (total 36 eyes in this plot), each dot represents a single clinic visit, green =CRYSTALSIGHT, blue = OCT.

	Cohort 1	Cohort 2
Trial objectives	Verify OCT versus CRYSTALSIGHT correlation (threshold score)	wAMD/DME recurrence detection - (intervention alerts)
Device	CRYSTALSIGHT camera with Tobii ET5L	CRYSTALSIGHT camera only OR Digitized amsler Grid
Physician interaction	Four times: 1. Registration 2. First follow up 3. 2nd follow up 4. Exit	PRN* regimen: 1. Registration 2. Monthly clinic visits 3. Intervention 4. Exit *(PRN scheduled clinic visits will proceed normally)
Size	100	220
Intended use	Clinic based	Home-based

In Cohort-1, the CRYSTALSIGHT system will be used in a clinical setting under the guidance of a trained healthcare professional to confirm the correlation between CRYSTALSIGHT and OCT in the same study participant longitudinally and establish a threshold for "deterioration."

Recruitment

1. **Eligibility Diagnosis**: The PI determine eligibility and will inform a potential participant (diagnosed with wAMD who is on a treatment regimen) to determine if CRYSTALSIGHT is an appropriate monitoring option.
2. **Enrolment**: If CRYSTALSIGHT is deemed appropriate for the patient, the PI or study coordinator will enroll the patient in the trial for the device and provide the patient with instructions for using the device.
3. **Training:** the study coordinator trains the participant on a CRYSTALSIGHT device to familiarise the patient with the device and ensures that the patient understands and follows the rules for home use.
4. **Initial monitoring:** The PI will start the participant on self-monitoring with CRYSTALSIGHT twice a week and monitor the participant's baseline gaze performance via the CRYSTALSIGHT electronic database.
5. **Maintenance Monitoring:** Once the participant has achieved a nominal baseline level of visual performance, the system will remind the participant to regularly monitor their visual performance with the CRYSTALSIGHT device at the scheduled frequency.

6. **Follow-up:** The PI will schedule regular follow-up appointments to monitor the participant's progress and adjust monitoring frequency as needed.

It is important to note that CRYSTALSIGHT does not work for all participants and it may take several months to detect disease relapse.

Study Schedule Table

Baseline Visit #1 Month 1	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) **Research Procedure** • CRYSTALSIGHT Eye Gaze Tracking for investigative arm and insurance of CRYSTALSIGHT device for home monitoring. OR • Amsler Grid for Amsler Grid arm
Follow Up Visit #2 Month 2 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #3 Month 3 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #4 Month 4 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)

Follow Up Visit #5 Month 5 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #6 Month 6 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #7 Month 7 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #8 Month 8 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #9 Month 9 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)
Follow Up Visit #10 Month 10 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review

Follow Up Visit #11 Month 11 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review
Study Exit Visit #12 Month 12 (+/- Four weeks)	**Standard Routine Care** • Visual Acuity (VA) • BCVA (Optional) • Optical Coherence Tomography (OCT) • Colour Fundus Photography • Clinical Consultant Review • Intravitreal Injections (IVT) (Optional)

Locations

Three study sites are proposed:

1. Dr. Dorothy L. Hitchmoth, PLLC, New London, United States
2. The Princess Alexandra Eye Pavilion in Edinburgh, Scotland, United Kingdom
3. Tan Tock Seng Hospital, Singapore

Timeframe

Estimated Start Date: June, 2025
Estimated Completion Date: August, 2026

Eligibility

Inclusion / exclusion criteria of this study are as follows.

Participation Requirements:
Genders: Both
Minimum Age: 55
Healthy Volunteers: No

Inclusion criteria

1. Subjects in the age group ≥ 55 to 99 years old.
2. Both genders
3. Able to understand verbal spoken instructions in British/American English, Chinese or Bahasa Melayu and demonstrate device functionality and implementation.
4. Able to turn on and connect the CRYSTALSIGHT device to a computer independently or with the help of family.
5. Subjects undergoing treatment for Wet-AMD without any signs and symptoms of recurrence of active AMD (AMD recurrence: choroidal neovascularisation,

intraretinal or subretinal fluid is present) with OCT lesion fluid volume more than 2 mm^2 or ILM height more than 300µm.
6. Ability to comply with the study protocol, in the investigator's judgment.
7. Subjects must be able to understand and provide informed consent. A signed informed consent form must be provided before any study assessments.

Exclusion criteria

1. Unable to understand verbal spoken instructions and demonstrate device functionality and implementation.
2. Unable to turn on and connect the CRYSTALSIGHT device to a computer independently.
3. Any ocular surgery in the previous 3 months, or vitrectomy in the previous 12 months
4. Any history of macular pathology unrelated to AMD affecting vision or contributing to the presence of intraretinal or subretinal fluid in the study eye
5. Any concurrent intraocular condition in the study eye that, in the opinion of the investigator, could either reduce the potential for visual improvement or require medical or surgical intervention during the study
6. Any prior or concomitant treatment for CNV or vitreomacular-interface abnormalities in the study eye.
7. History of idiopathic or autoimmune-associated uveitis in either eye
8. Active ocular inflammation or suspected or active ocular or periocular infection in either eye.

Study population: patients with recurrent vision problems diagnosed with active Wet-AMD at TTSH eye clinics.

Pre-specified clinical outcome: The prespecified adverse clinical outcome used in this study will be the **recurrence of Active Wet AMD,** which will be identified by an increase in central retinal thickness (CRT) of at least 50 microns or a loss of best-corrected VA of 5 letters or more.

Training

To prepare for home use of the CRYSTALSIGHT device, the following processes are performed in the clinic:

- The examining physician or study coordinator will unpack a CRYSTALSIGHT training unit for the patient to help the patient understand the device and ensure that the home user understands the device, its purpose, and how it works. Instructions on how to set it up at home include connecting the device to a laptop with an Internet connection.
- The study coordinator will explain the testing procedure in the language the patient knows (English, Chinese, Malay, and Tamil). The study representative from the clinical trial site hospital will train the subject on using the device. This involves demonstrating how to take the test and interpret the results. The user should learn the test procedure, including how to prepare for the test, perform the test, and interpret the results.

- A training video is then played to illustrate how the device works. The study participant must watch the 5-minute video.
- After watching the video, the user should be familiar with the device's various parts, such as how to position the device on a computer best and how to launch the test program in the computer's browser.
- Practice with the device: then the user practices using it on himself/herself to get a feel for how it works. This will help him/her become more confident and familiar with the CRYSTALSIGHT device.
- **Weekly Use:** The subject will be instructed to use the CRYSTALSIGHT device twice a week, usually in the evening or when they are most likely to be relaxed and focused.
- All records are sent electronically to Occutrack's cloud server. The records include each user's unique identification number (UUID), vision test results, and the date, time, and results of each test. This helps them track their progress and identify trends or patterns in their wet AMD disease.

Troubleshooting

If a participant experiences technical difficulties, the study coordinator is available for teleconsultation on weekdays from 9 am to 5 pm during office hours. For the Cohort 2 study, there are several options for remediation.

1. Participants may contact their physician, the study coordinator PI, or a trained health care professional if they have questions or concerns about using the device or interpreting the results.
2. Read the manual: The participant can carefully read the manual included with the device. The manual provides instructions on how to properly use the device, interpret results, and troubleshoot common problems.
3. Troubleshooting: The subject should be familiar with common problems that may occur when using the CRYSTALSIGHT device and how to correct them. These may be problems with the camera, mounting position, or software interface.
4. Follow best practices: The participant should follow best practices when using the device, including placement, head position, and attention to stimulation targets on the screen.

By following these steps, a new user can master the CRYSTALSIGHT health monitoring device and effectively manage their AMD condition.

How are they going to get the device

One CRYSTALSIGHT boxed unit will be signed over to the study participant to bring home after the recruitment administration is done during the regular clinic check-up and when the participant has agreed and signed the Informed Consent Form (ICF) to be included in the study.

System reminders

A study coordinator will monitor the electronic records system and will call the participant to conduct a self-test at home if they miss the test by 1 day. A system

reminder will automatically send a message and email to remind the user to take the test if a scheduled self-test is missed by a day.

Results and reporting: The results of the tests will be transmitted to a secure server where they will be analyzed by the principal investigator and study coordinator. If any changes in vision are detected, the subject will be contacted by the study coordinator and a follow-up appointment will be scheduled.

Sample size calculation:

According to the workflow, all participants will have routine visits to clinic with OCT scans performed once every 4 weeks. Participants randomised into the CRYSTALSIGHT group will have measurements taken twice a week if the testing results are all negative. In case of a positive result with CRYSTALSIGHT, another test will be done on the next day. Participants will be recalled for review after two consecutive positive results are presented. Depending on the pathology presented on the OCT scan, IVT may be given for disease management. On the other hand, participants randomised into the Amsler Grid group will be evaluated by Amsler Grid and by OCT.

For participants in the CRYSTALSIGHT group, each participant will have a testing result by CRYSTALSIGNT and by OCT every 4 weeks or less if the positive result triggers a clinical visit. The result is considered correct if it is consistent with the findings of the OCT scan. During the one-year study period, the total number of correct results generated by CRYSTALSIGHT will be counted and the accuracy for these participants will be calculated as number of correct results divided by the total number of clinical visit. For participants in the Amsler Grid group, the accuracy for each participant will also be calculated.

According to literature, the accuracy of Amsler Grid in detecting disease activity was about 80%, we will assume that CRYSTALSIGHT has the same accuracy. For the Singapore population, we will also assume that standard deviation of the accuracy to be 0.12 and setting the maximum allowable difference in accuracy (non-inferiority margin) between the two groups to be 0.09, with one-sided type 1 error of 0.025 and a power of 0.8, a total of 52 participants will be required (26 per group). Considering of 15% attrition rate, a total of 60 participants will be required.

For global study, we assume a higher standard deviation of the accuracy to be 0.21 and a dropout rate of 21%, a total of 220 participants will be required (110 per group).