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Assessment of the EyeVdoc App

Submission date 23/08/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/08/2023	**Overall study status** Completed	
Last Edited 29/08/2023	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Common eye conditions account for a significant number of clinical visits, with health care clinicians – these maybe GP, optometrist, pharmacists, nurse, AHP or A&E departments. In some areas of the UK there are NHS funded services, for patients to present to a community optometrist (these are called Minor Eye Care services, or Optometry first) the outcome of these visits, for common external eye conditions, is often reassurance or advice on self-management. Where optometry services are not available, it can result in patients attending multiple visits with various clinicians. Considering the capacity and financial pressures on the NHS, this tool could help support capacity issues and reduce financial costs for the NHS.

Who can participate?
Adults over 18 years, with a range of eye conditions.

What does the study involve?
Participants are selected after they have been seen by an eye care health professional. The study involves visiting the website https://www.eyevdoc.com. Participants will be asked to complete the online consenting process, then enter some information about age, gender, ethnicity and then take and upload images of the eye using a smartphone camera.

What are the possible benefits and risks of participating?
None

Where is the study run from?
EyeV Ltd (UK)

When is the study starting and how long is it expected to run for?
August 2023 to October 2024

Who is funding the study?
EyeV Ltd (UK)

Who is the main contact?
Adam Holliday, adam@eyev.health

Study website
https://www.eyevdoc.com/

Contact information

Type(s)
Principal Investigator

Contact name
Mr Adam Holliday

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
To assess the precision of a machine learning tool, to diagnose a range of common external eye conditions

Study objectives
To determine the precision of a machine learning tool, to diagnose a range of common external eye conditions using smartphone camera.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, HRA (United Kingdom)

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Optician

Study type(s)
Diagnostic

Participant information sheet
https://www.eyevdoc.com/participant-information/

Health condition(s) or problem(s) studied
Ptosis, Dermatochalasis, Blepharochalasis, Allergic conjunctivitis, Bacterial conjunctivitis, Dry eye, Anterior uveitis, External hordeolum, Internal hordeolum, Entropion, Ectropion, Blepharitis, Pterygium, Pingquela, Anisocoria, Sub conjunctival haemorrhage, Episcleritis

Interventions
There are two arms to this study, for data collection.

Retrospective analysis of external eye images
From an existing clinical service (Leicestershire, COVID urgent eye service) using images which were provided by patients as part of their clinical care and which a diagnosis was made by a clinician. Consent to use images was given by patients, for use in their clinical care but not for research. A new consent process would be undertaken for use of the images for research process.

Prospective data collection
Patient presents to a community optometrists/ophthalmologist, who performs a clinical assessment, provides diagnosis, treatment and management. If the patient has one of the eye conditions being considered, the clinician will discuss the study with the patient and if interested in participating, provides the participant with the PIS EyeVdoc leaflet. The clinician will indicate on the PIS EyeVdoc leaflet the clinical diagnosis(s). The participant can then enrol into the online study at a convenient time after the clinical visit.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
EyeVdoc App

Primary outcome measure
Precision of the EyeVdoc app measured using the EyeVdoc app diagnosis compared to a clinical diagnosis at a single time point.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
23/08/2023

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Age: 18 yrs and over
2. Ability to consent
3. Being diagnosed with one of the below external eye conditions
3.1. Ptosis
3.2. Dermatochalasis
3.3. Blepharochalasis
3.4. Allergic conjunctivitis
3.5. Bacterial conjunctivitis
3.6. Dry eye
3.7. Anterior uveitis
3.8. External hordeolum
3.9. Internal hordeolum
3.10. Entropion
3.11. Ectropion
3.12. Blepharitis
3.13. Pterygium
3.14. Pingquela
3.15. Anisocoria
3.16. Sub conjunctival haemorrhage
3.17. Episcleritis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
No smartphone

Date of first enrolment
01/10/2023

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Opthalmology (calderdale Royal Hospital)
The Calderdale Royal Hospital
Huddersfield Road
Halifax
United Kingdom
HX3 0PW

Sponsor information

Organisation
EyeV Ltd

Sponsor details
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Sponsor type
Industry

Website
https://www.eye.health

Funder(s)

Funder type
Industry

Funder Name
EyeV Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Adam Holliday adam@eyev.health

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	21/07/2023	29/08/2023	No	No