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Using AI to detect and predict eye damage from hydroxychloroquine

Submission date
16/02/2025

Registration date
20/02/2025

Last Edited
20/02/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hydroxychloroquine is a medication that can cause eye damage (retinal toxicity) in some patients. Detecting this damage early is difficult and depends on the doctor's interpretation of various eye tests. This study aims to use artificial intelligence (AI) to automate the analysis of these tests, making it easier to detect eye damage early and reduce the workload for eye doctors.

Who can participate?
Patients who have been taking hydroxychloroquine for more than 10 years are eligible to participate in this study.

What does the study involve?
Participants will undergo the same eye tests that are typically used to screen for hydroxychloroquine toxicity. These tests include fundus photography and optical coherence tomography with autofluorescence. The data collected will be anonymized and analyzed using AI to detect any signs of eye damage.

What are the possible benefits and risks of participating?
There are no risks associated with participating in this study, as the tests performed are standard procedures. Participants may benefit from early detection of eye damage if the AI algorithm proves to be successful.

Where is the study run from?
Centro Hospitalar de Lisboa Central (Portugal)

When is the study starting and how long is it expected to run for?
August 2023 to February 2025

Who is funding the study?
The study is funded by grants from Grupo de Estudos de Retina, Sociedade Portuguesa de Oftalmologia, Centro Hospitalar de Lisboa Central, and Alphasigma (Portugal)

Who is the main contact?
Rita Anjos, rita.s.anjos@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Artificial intelligence in the detection and prediction of hydroxychloroquine maculopathy

Acronym
PLAQUINAI

Study objectives
We hypothesize that HCQ toxicity can be detected with a deep learning system with OCT

Ethics approval required
Ethics approval required

Ethics approval(s)

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Hydroxychloroquine maculopathy

Interventions
Patients on long-term hydroxychloroquine (HCQ) therapy will have an optical coherence tomography (OCT) examination. Controls (no HCQ maculopathy) and toxicity (HCQ maculopathy) will be selected. OCT scans will be analysed by RETINAI algorithm.

Intervention Type
Other

Primary outcome(s)
Age, sex, weight, total cumulative HCQ/CHLOROQUINE dose; daily HCQ/CHLOROQUINE dose, time of HCQ/CHLOROQUINE use, baseline disease for HCQ/CHLOROQUINE , Other systemic diseases, Steroid use and dose, immunosuppressant, other medications and dose, ocular disease, ocular medication collected from patients notes as well as interviews during normal consultations

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
20/02/2025

Eligibility

Key inclusion criteria
Case group:
Patients with diagnosis of HCQ or Chloroquine toxicity

Control group:
Patients with > 10 years of HCQ intake

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

Patients with ocular diseases that may mimic HCQ maculopathy or interfere with its screening

Date of first enrolment

01/08/2024

Date of final enrolment

19/02/2025

Locations

Countries of recruitment

Portugal

Study participating centre
Centro Hospitalar de Lisboa Central
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Sponsor information

Organisation

Centro Hospitalar de Lisboa Central

ROR

https://ror.org/00k6r3f30

Funder(s)

Funder type
Research organisation

Funder Name
Grupo de estudos de retina (GER)

Funder Name
Sociedade Portuguesa de Oftalmologia (SPO)

Funder Name
Centro Hospitalar de Lisboa Central

Funder Name
Alphasigma

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Rita Anjos rita.s.anjos@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes