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Using AI to detect and predict eye damage from hydroxychloroquine

Submission date	Recruitment status	[_] Prospectively registered
16/02/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2025	Eye Diseases	[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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Approved 28/12/2023, Ethics commission of Centro Hospitalar de Lisboa Central (R. José António Serrano, 1150-199 Lisboa, Lisboa, 1150-199, Portugal; +351914535963; rita.s.anjos@gmail.com), ref: 1304/2022

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
100

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
R. José António Serrano, 1150-199 Lisboa
Lisboa
Portugal
1150-199

Sponsor information

Organisation
Centro Hospitalar de Lisboa Central

Sponsor details
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+351 213 596 402
projetos.inv@chlc.min-saude.pt

Sponsor type
Hospital/treatment centre

Website
http://www.chlc.min-saude.pt/homepage.aspx?menuid=1

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

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

Intention to publish date
01/06/2025

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