ISRCTN11308648 https://doi.org/10.1186/ISRCTN11308648

# 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 | [ ] 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

### Contact name
Dr Rita Anjos

### ORCID ID
https://orcid.org/0000-0002-9058-5836

### Contact details
R. José António Serrano
Lisboa
Portugal
1150-199
+351 935619454
Rita.anjos@ulssjose.min-saude.pt

# Additional identifiers

# 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

### Primary study design
Observational

### Study design
Observational cross-sectional cohort study

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

# 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