

Study of a device for detecting diabetic eye disease

Submission date 28/12/2021	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/12/2021	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/06/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic retinopathy is a complication of diabetes caused by high blood sugar levels damaging the back of the eye (the retina). The EyeFundusScope is a smartphone-based eye fundus camera that has been developed to early detect diabetic retinopathy. This device can be used at home or in the offices of several health professionals who regularly have contact with patients with diabetes, such as family physicians and general practitioners, endocrinologists, nurses or optometrists. The aim of this study is to find out whether the EyeFundusScope can be used by physicians and nurses who are not specialists in ophthalmology to screen patients with diabetes for diabetic retinopathy.

Who can participate?

Patients aged 18-90 years old with diabetes

What does the study involve?

Physicians and nurses who are not specialised in ophthalmology will take pictures of patients' retinas with the EyeFundusScope.

What are the possible benefits and risks of participating?

Benefits: free ophthalmology consultation if the test result with EyeFundusScope is positive for diabetic retinopathy or other important findings, and reinforcement of the need to attend the next screening by the Portuguese National Health Service, even if the test result with EyeFundusScope is negative.

Risks: No significant risks are foreseen arising from participation in this study and the possible risks are mitigated by the researchers through measures of risk management.

Where is the study run from?

CUF Descobertas Hospital (Portugal)

When is the study starting and how long is it expected to run for?

September 2019 to November 2022

Who is funding the study?

This work is supported by "EyeFundusScopeNEO: Demonstration of EyeFundusScope with Non-Expert Ophthalmology Users", co-funded by Portugal 2020, framed under the Operational Program Competitiveness and Internationalization (COMPETE 2020) and European Regional Development Fund from European Union, with operation code POCI-01-0247-FEDER-038400.

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

EFS-A008/A009

Study information

Scientific Title

Implementation and evaluation of a mobile retinal image acquisition system for screening diabetic retinopathy

Study objectives

A smartphone-based handheld eye fundus camera can be used by physicians and nurses not specialists in ophthalmology to screen individuals with diabetes for diabetic retinopathy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 31/07/2018, Ethics Commission of ARS Norte (Rua de Santa Catarina, 1288, 4000-447 Porto, Portugal; +351 22 041 10 00; etica@arsnorte.min-saude.pt), ref: 115/2018
2. Approved 21/12/2019, Ethics Committee of CUF Descobertas Hospital (Rua Mário Botas, 1998-018 Lisbon, Portugal; +351 (0)21 002 5200; marta.barreiros@cuf.pt), ref: not applicable

Study design

Cross-sectional study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Diabetic retinopathy

Interventions

In this study, individuals with diabetes will be assessed for diabetic retinopathy with the smartphone-based handheld fundus camera EyeFundusScope (Fraunhofer AICOS, Portugal) operated by non-ophthalmic physicians and nurses.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

Diagnostic accuracy of EyeFundusScope for diabetic retinopathy screening, measured using sensitivity, specificity, predictive values and likelihood ratios at the time of retinal image acquisition

Key secondary outcome(s)

1. Image quality measured in four levels and classified by ophthalmologists at the time of retinal image acquisition
2. Technological functioning measured using the number of eyes in which it was not possible to acquire images, and the number of technical failures of both the EyeFundusScope and the information system, at the time of retinal image acquisition
3. Usability of the EyeFundusScope measured using the proportion of healthcare professionals who report ease of use, the score of the System Usability Scale, qualitative analyses of the observation and the mean time required to perform retinal image acquisition with the EyeFundusScope, at the time of retinal image acquisition
4. Acceptance of the EyeFundusScope measured using questionnaires and qualitative analysis of interviews and observations at the time of retinal image acquisition
5. The association of patients' clinical characteristics with the accuracy and the quality of the images of the EyeFundusScope, measured using odds ratios at the time of retinal image acquisition
6. Inter and intra-operator agreement and reliability of the EyeFundusScope measured using kappa statistics and overall observed agreement at the time of retinal image acquisition
7. Ground truth optimization for the training of the algorithms before the calculation of measures listed above

Completion date

30/11/2022

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Diabetes mellitus diagnosis
2. 18-90 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Key exclusion criteria

1. Blindness
2. Strabismus
3. Retinal detachment
4. Blepharospasm
5. No autonomy to remain seated
6. Sensitivity to light due to medication, recent photodynamic therapy, or other reason
7. Pregnant or breastfeeding women

Date of first enrolment

15/06/2022

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

Portugal

Study participating centre

CUF Tejo Hospital

Av. 24 de Julho 171A

Lisbon

Portugal

1350-352

Study participating centre

ACES Grande Porto II - Gondomar

Rua Actor Mário Viegas

Rio Tinto

Porto

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4435-076

Sponsor information

Organisation

Fraunhofer Portugal Research

ROR

<https://ror.org/05eqk2j25>

Funder(s)

Funder type

Government

Funder Name

Portugal 2020, framed under the Operational Program Competitiveness and Internationalization (COMPETE 2020) and European Regional Development Fund from European Union, with operation code POCI-01-0247-FEDER-038400

Results and Publications

Individual participant data (IPD) sharing plan

Participant-level data will be stored at the sponsor's information system and will not be made publicly available to protect participant privacy, as the study site is relatively small within the Portuguese healthcare system.

IPD sharing plan summary

Not expected to be made available