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Study of a device for detecting diabetic eye disease

Submission date 28/12/2021	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/12/2021	**Overall study status** Stopped	
Last Edited 18/06/2024	**Condition category** Eye Diseases	

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 EyeFundusSope 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Screening

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

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

Secondary outcome measures
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

Overall study start date
01/09/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
578

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

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Sponsor information

Organisation
Fraunhofer Portugal Research

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Sponsor type
Research organisation

Website
https://www.aicos.fraunhofer.pt/en/home.html

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

Publication and dissemination plan
1. Study protocol accepted for publication in a journal
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2023

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