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Western Province Diabetic Retinopathy Screening Project (WPDRSP)

Submission date	**Recruitment status**	[_] Prospectively registered
12/03/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims

The Western province of Sri Lanka has recorded the highest proportion of people with diabetes (1 in 5) in the country. Diabetes can cause sight loss due to changes in the blood vessels at the back of the eye, leading to sight loss. This is called 'diabetic retinopathy'. This can be prevented by early screening and treatment. Though there is a high number of people with diabetes in the Western province there is no systematic screening program to identify those who are at risk of losing sight. A survey in this region found that more than 750,000 required screening visits were not done in this region per year.

Who can participate?

Patients with diabetes (PwDM) (> 18 years of age) without previous DRS at an eye clinic will be eligible to participate, after giving written informed consent. Eligible participants will be recruited by trained research assistants when PwDM present for routine medical care at the main tertiary centre in Colombo. The PwDM with previous retinal screening, DR related treatment (laser treatment, intra-vitreal injections and pars-plana-vitrectomy), and those who were currently under any DRSP or treatment will be excluded from study.

What does the study involve?

This study will provide easily accessible innovative screening modality at the medical clinic to overcome this public health issue. We aimed to assess whether the physicians are capable and accurate in identifying the changes of the diabetic retinopathy using a simple hand-held camera. To assess the accuracy of detecting the level of diabetic retinopathy two trained physicians will capture images when the people with diabetes present at the medical clinic. They will do capture images both before and after the dilatation of pupils. The digital retinal imaging is a well-established practice in high-income countries for eye screening and there are no harmful effects of this method. The physicians will identify the level of diabetic retinopathy according to a locally adopted classification system. After the imaging, the people with diabetes will undergo more detailed eye examination by a specialist retinologists to confirm the diagnosis. Afterwards, the retinologist's finding will be compared with each physician finding to assess the level of accuracy. If the physicians can diagnose the diabetic retinopathy up to an acceptable level, we

plan to implement this as a screening strategy to identify the diabetic retinopathy at the medical clinic level. This will provide more accessible screening modality for the community in need in this region.

What are the possible benefits and risks of participating?
This study is one of the first studies conducted in Sri Lanka on checking for eyes for diabetic eye ailments. Benefits are that particpants will undergo full eye examination by a specialist eye doctor and get the opportunity to identify any other eye diseases such as cataract (whiteness of the eye) or eye pressure (glaucoma). As well as all the necessary further investigations and treatment facilities for any treatable eye condition identified, free of charge at the National Eye Hospital. Participants are entitled to receive a per-diem for participation.
There are no harmful effects on eye examination using the hand held eye camera. These cameras has been used in many other countries successfully. There may be some discomfort due to the white flashing light of the camera for few seconds and after putting the eye drops to dilate the pupils. A transient blurring for 1-2 hours after the dilatation of pupils. The pupil dilatation is essential to have a better look at the back of the eyes. Rarely, dilatation of the pupils can lead to an increase in eye pressure. However, we assess risk for this when recruiting to the study and we will take all precautions before instilling the eye drops.

Where is the study run from?
1. National Eye Hospital, Columbo
2. National Hospital of Sri Lanka, Columbo

When is the study starting and how long is it expected to run for?
August 2017 to April 2018

Who is funding the study?
Queen Elizabeth Diamond Jubilee Trust (UK)

Who is the main contact?
Dr. Mapa Piyasena, Prabhath.piyasena@lshtm.ac.uk

Study website
https://www.researchprotocols.org/2018/12/e10900

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
(IRRID): PRR1-10.2196/10900

Study information

Scientific Title
Diagnostic Test Accuracy of Diabetic Retinopathy Screening by Physician Graders Using a Hand-held Non-Mydriatic Retinal Camera at a Tertiary Level Medical Clinic

Acronym
WPDRSP

Study objectives
The hypothesis is that trained physicians would accurately identify those who have a referable level of retinopathy at the medical clinics using hand-held digital retinal camera

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2017, Ethics Review Committee of the London School of Hygiene and Tropical Medicine (Keppel Street, London, WC1E 7HT; +44 (0) 20 7636 8636; Ethics@lshtm.ac.uk), ref: 12072.
Approved 10/03/2017, Ethics Review Committee of the National Eye Hospital (National Eye Hospital, Colombo-10, Sri Lanka; +94 11 2693911 / EXT 300; nehercsecretary@gmail.com), ref: ERC/NEH/2017/32

Study design
Observational screening intervention validation study

Primary study design
Observational

Secondary study design
Diagnostic test accuracy testing

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available on-line, Can be received from - MMPN Piyasena - Research Fellow - London School of Hygiene and Tropical Medicine - UK - email - Prabhath.piyasena@lshtm.ac.uk

Health condition(s) or problem(s) studied
Status of the diabetic retinopathy among the diagnosed people with diabetes at a tertiary level medical clinic

Interventions
Baseline data collection - The included participants baseline data will be collected by a research assistant.
Interventions – The participants would undergo two-field digital retinal imaging by two trained physician graders.
1. The same participant would undergo the same two-field digital retinal imaging by each physician grader without pupil dilatation
2. Then, the participants would undergo dilation of pupils using phenylephrine eye drops and prepare for dilated photography. Here, the participants would undergo mydriatic two-field imaging by both physician graders. Captured images will be coded and stored by the research assistants. The coded image sets will be given back to each physician grader for grading according to a locally adopted classification system.

After the index test imaging participants will be invited for reference test grading (within a 4 weeks period) by an experienced retinologists at a tertiary level eye clinic. The retinologist's diabetic retinopathy gradings will be documented in a standard retinal diagram. The retinologist is also blinded for the history of the participants. Afterwards, diagnostic accuracy will be calculated for each grader and each pupil status compared with the reference standard.

Intervention Type
Other

Primary outcome measure
1. Diagnostic test accuracy (sensitivity and specificity) of detecting a defined level of diabetic retinopathy by a physician grader, by comparison with the diagnosis by a specialist retinologist (to take place up to a maximum of 4 weeks after the physician diagnostic test.

Secondary outcome measures
1. Other measures of diagnostic test accuracy of detecting a defined level of diabetic retinopathy by the physician graders - 1) negative predictive value, 2) positive predictive value), AND agreement analysis (k-Kappa).

Overall study start date
01/01/2016

Completion date
01/08/2018

Eligibility

Key inclusion criteria
1. Diabetes (PwDM)
2. > 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The sample size (n=506) was calculated based on 95% confidence intervals, 10% margin of error, expected sensitivity 70% and prevalence of moderate NPDR among PwDM of 20%. This included an additional 25% to take account of ungradable images. Interim analysis has been undertaken to ascertain the level of ungradable images (i.e. <50% of the retina visible) and the sample size was increased to n=700 due to high proportion of technical failures in imaging.

Total final enrolment
700

Key exclusion criteria
1. Previous diabetic retinopathy screening and treatment.

Date of first enrolment
01/08/2017

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Sri Lanka

Study participating centre
National Eye Hospital
Deans Road
Colombo
Sri Lanka
01000

Study participating centre
National Hospital of Sri Lanka
Professorial Medical Unit
Regent street
Colombo
Sri Lanka
00700

Sponsor information

Organisation
Commonwealth Eye Health Consortium

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Sponsor type
Research organisation

Website
http://cehc.lshtm.ac.uk/phd-fellows/

Funder(s)

Funder type
Charity

Funder Name
Queen Elizabeth Diamond Jubilee Trust

Results and Publications

Publication and dissemination plan
The protocol paper has been published in JMIR (JMIR Res Protoc 2018;7(12):e10900 doi:10.2196/10900). The results manuscript is under review of BMC-Ophthalmology - Open source.

Intention to publish date
01/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/12/2018		Yes	No
Results article		08/04/2019	24/09/2021	Yes	No