

# Western Province Diabetic Retinopathy Screening Project (WPDRSP)

<b>Submission date</b> 12/03/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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-vitreous 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 participants 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

## Contact information

**Type(s)**

Public

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

(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

## **Study type(s)**

Diagnostic

## **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(s)**

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).

## **Key secondary outcome(s)**

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).

## **Completion date**

01/08/2018

# Eligibility

## Key inclusion criteria

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

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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

## Funder(s)

### Funder type

Charity

### Funder Name

Queen Elizabeth Diamond Jubilee Trust

## Results and Publications

### 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?
<a href="#">Results article</a>		08/04/2019	24/09/2021	Yes	No
<a href="#">Protocol article</a>	protocol	10/12/2018		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes