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Complex interventions to implement a diabetic retinopathy care pathway in the public health system in Kerala: a hybrid effectiveness-implementation study (Nayanaadram project)

Submission date
04/06/2018

Recruitment status
No longer recruiting

Registration date
06/07/2018

Overall study status
Completed

Last Edited
28/06/2022

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 (retina), which can cause blindness if left undiagnosed and untreated. Several developed countries with established diabetic retinopathy screening programmes and effective treatment pathways have shown that it is clinically and cost-effective to deliver this service to decrease visual impairment in people with diabetes. In this study, the aim is to evaluate the effectiveness of introducing screening and treatment pathways in the public system in Kerala by adapting care pathways in the developed countries to local needs and resources. The researchers intend to introduce a complex intervention of screening for diabetic retinopathy at the primary care level, laser treatment at district hospitals and complex referrals to the tertiary centres by increasing research and service capacity and capability. The quality and delivery of the intervention is also assessed at each sector of the care pathway to evaluate whether the study is delivered as intended.

Who can participate?
Patients with diabetes

What does the study involve?
The interventions are at three levels of care. The study introduces pragmatic interventions to initiate a diabetic retinopathy care pathway across primary, secondary and tertiary care to ensure:
1. Diabetic retinopathy screening of patients with diabetes registered in the NCD register (primary care): interventions include training of nurses and doctors at FHCs on capturing retinal images, data collection on a minimal dataset and increasing infrastructure facilities for transfer of retinal images to RIO
2. Prompt referral for timely treatment of sight threatening diabetic retinopathy to district hospitals (secondary care) and tertiary centres depending on the severity of the diabetic retinopathy. Interventions include training ASHA workers to identify and accompany screen-

positive patients for treatment. The effect of incentivisation on the ASHA workers is also evaluated. The ophthalmologists in the district hospitals are trained to deliver laser treatment and laser equipment is installed in some district hospitals.
3. Treatment of patients with sight threatening DR (at secondary and tertiary care): a reading centre is set up to grade all retinal images sent in from FHCs. The optometrists are trained to grade the images using the International Diabetic Retinopathy severity grading. Laser training is provided to ophthalmologists from secondary care. Research capacity is built in all 3 levels of care and activities range from quality improvement projects to publications on the care pathway. The change in the numbers of patients identified, screened and treated for sight threatening diabetic retinopathy as a result of these interventions is measured 6 months after initiation of the project.

What are the possible benefits and risks of participating?
Diabetic retinopathy is an asymptomatic disease until the disease is advanced and timely identification and treatment of sight threatening disease reduces the risk of blindness due to diabetic retinopathy. Therefore, patients have to be screened for diabetic retinopathy. This screening process is non-existent in the public system in Kerala and the diabetic retinopathy care pathway is not established. Participating in this study will enable patients with a diagnosis of diabetes and registered in the Non-Communicable Disease Register to be screened and offered timely treatment for this potentially blinding condition. The risks will include patients identified of this condition or any other blinding condition refusing or delaying treatment despite being offered.

Where is the study run from?
Directorate of Health Services (India)

When is the study starting and how long is it expected to run for?
October 2017 to July 2019

Who is funding the study?
Global Challenges Research Funds - United Kingdom Research and Innovation

Who is the main contact?
Prof. Sobha Sivaprasad

Contact information

Type(s)
Scientific

Contact name
Prof Sobha Sivaprasad

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Additional identifiers

Protocol serial number
Ornate India Protocol 1.0

Study information

Scientific Title
Complex interventions to implement a diabetic retinopathy care pathway in the public health system in Kerala: a hybrid effectiveness-implementation study (Nayanaadram project)

Acronym
Nayanaadram project

Study objectives
Rationale - Improving research and service capacity and capability will improve diabetic retinopathy care pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee General Hospital, Thiruvananthapuram, 17/05/2018

Study design
Hybrid effectiveness-implementation study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Diabetic retinopathy

Interventions
The interventions will be at 3 levels of care. The study will introduce pragmatic interventions to initiate a DR care pathway across primary, secondary and tertiary care to ensure:
1. DR screening of patients with diabetes registered in the NCD register (primary care): Interventions will include training of nurses and doctors at FHCs on capturing retinal images, data collection on a minimal dataset and increasing infrastructure facilities for transfer of retinal images to RIO
2. Prompt referral for timely treatment of sight threatening DR to district hospitals (secondary care) and tertiary centres depending on the severity of the diabetic retinopathy. Interventions will include training ASHA workers to identify and accompany screen-positive patients for treatment. The effect of incentivisation on the ASHA workers will also be evaluated. The ophthalmologists in the district hospitals will be trained to deliver laser treatment and laser equipments will be installed in some district hospitals.
3. Treatment of patients with sight threatening DR (at secondary and tertiary care): a reading

centre will be set up to grade all retinal images sent in from FHCs. The optometrists will be trained to grade the images using the International Diabetic Retinopathy severity grading. Laser training will be provided to ophthalmologists from secondary care. Research capacity will be built in all 3 levels of care and activities will range from quality improvement projects to publications on the care pathway.

The change in the numbers of patients identified, screened and treated for sight threatening diabetic retinopathy as a result of these interventions will be measured 6 months after initiation of the project.

Intervention Type
Not Specified

Primary outcome(s)
The number of people with diabetes that were identified, screened and treated for sight threatening retinopathy, measured at 6 months following the interventions

Key secondary outcome(s))
Measured at 6 months following the interventions:
1. Effectiveness of intervention at primary care level – increase in uptake of DR screening at FHCs as a result of these interventions
2. Effectiveness of interventions at secondary care level – increase in numbers of people treated for STDR in secondary care
3. Effectiveness of intervention at tertiary care level – increase in numbers of patients referred for treatment as a result of DR screening at FHC
4. Factors determining effectiveness of screening and treatment uptake e.g. age groups, gender, FHC
5. Clinical and cost-effectiveness of training and incentivisation of the ASHA workers - completeness of the NCD register in each FHC and the increase in screening and treatment of DR post-training and incentivisation of the ASHA workers

Other outcomes:
6. Prevalence of diabetes in each FHC in comparison to the estimated 1:5 adult population in Kerala presumed to be diabetic
7. Prevalence of other complications of diabetes including those with nephropathy, stroke and myocardial infarction identified through the diabetes register
8. Change in life satisfaction questionnaires after the intervention
9. Treatment outcomes of people with STDR
10. Model based economic analysis of the DR screening and treatment pathway

Completion date
01/07/2020

Eligibility

Key inclusion criteria
People with diabetes

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
5339

Key exclusion criteria
Patients who do not wish to be screened or treated for diabetic retinopathy

Date of first enrolment
01/01/2019

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
India

Study participating centre
Directorate of Health Services
General Hospital Junction
Thiruvananthapuram
India
695035

Sponsor information

Organisation
Directorate of Health Services

Funder(s)

Funder type
Government

Funder Name
Global Challenges Research Funds - United Kingdom Research and Innovation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/12/2021	28/06/2022	Yes	No
Protocol article		28/06/2021	30/06/2021	Yes	No