ISRCTN57962668 https://doi.org/10.1186/ISRCTN57962668

Multi-centre risk-based screening for diabetes and its complications

Submission date
18/08/2018

Recruitment status
No longer recruiting

Registration date
24/09/2018

Overall study status
Completed

Last Edited
07/12/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
This study will test the accuracy of a number of non-laboratory tests to diagnose diabetes and pre-diabetes and their associated complications compared to the standard laboratory tests and retinal photographic images grading for diabetic retinopathy.
The tests will be done in 48,000 adult individuals at their homes across 20 regions in India and will include both rural and urban areas. In addition, special communities will also be included to ensure generalisability of the results and identify any high risks groups for diabetes and/or its complications.
The interventions are non-laboratory tests and these will be compared to the standard blood tests to test how accurately and cost-effectively these tests can identify people with diabetes, pre diabetes and those with complications of diabetes.
The standard tests are blood sugar tests, lipid profile and urine test for microalbuminuria. There are various blood tests available to test for diabetes and pre-diabetes and the ideal clinical and cost-effective point of care laboratory test will also be evaluated.
The most cost -effective tests may not be the most accurate tests. So the study will also evaluate the rate of false or over diagnosis of diabetes and its complications with non-laboratory tests compared to laboratory tests.
Participants whose retinal photographs are graded for treatable retinopathy will be treated at the research sites. The study will allow us to report the overall prevalence and regional prevalence of diabetic retinopathy and sight threatening retinopathy. As we are using a point of care retinal camera, the study will also evaluate the feasibility of this camera in terms of gradebale images, acceptability, the need for mydriatic eye examination. A diabetic care pathway will be established and a process evaluation of this pathway will be reported.
The anonymised data will be collected on a web-based database and will include the whole pathway from the point of identification of patient to treatment of diabetic retinopathy if required.
The study will also increase public awareness of diabetes and its complications and barriers and enhancers of the diabetes care pathway will be evaluated qualitatively.

Background and study aims
Current diagnoses of diabetes and its complications such as retinopathy (eye problems), diabetic kidney disease, stroke and ischaemic heart disease and diabetic foot are based on expensive tools and laboratory tests. Therefore, these are not accessible to many people around the world,

meaning that we have a lack of data on the prevalence of diabetic retinopathy or a diabetic care pathway that is cost-effective in low and medium income countries. Non-laboratory tests may be more cost-effective than laboratory tests, and therefore may be more accessible in these countries.
This UK-India collaborative study will test whether non-laboratory tests could be accurately used to diagnose diabetes and each complication of diabetes. The aim is to find the most cost-effective test, or tests that include questionnaires and demographic data that could accurately be used, instead of the current standard tests that are not accessible to several people around the world because of the costs. The study will also allow us to report the overall prevalence and regional prevalence of diabetic retinopathy and sight-threatening retinopathy in India using a point of care retinal camera. By conducting a national study, we will also be able to evaluate the feasibility of a diabetic care pathway in India.

Who can participate?
The non-laboratory tests and standard tests will be done in 48,000 adult individuals by home visits by trained health workers across 20 regions in India and will include both rural and urban areas. In addition, special communities will also be included to ensure that the results may be used across all people with diabetes and/or its complications.

What does the study involve?
Health workers will conduct house to house visits in the study regions to ask participants to complete questionnaires and blood/urine tests, and capture retinal images using point of care kits. Anonymised data from the study will be sent to the UK for statistical and health economics analysis and for joint reporting of study findings.

What are the possible benefits and risks of participating?
The public awareness of diabetes and its complications will increase and people with newly identified conditions as a result of this study can be promptly treated. There are no known risks to participants taking part in this study.

Where is the study run from?
Vision Research Foundation, Chennai, India

When is the study starting and how long is it expected to run for?
October 2017 to September 2021

Who is funding the study?
The Global Challenge Research Fund, Medical Research Council (UK)

Who is the main contact?
Professor Sobha Sivaprasad, Moorfields Eye Hospital, London, UK
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Contact information

Type(s)
Scientific

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Scientific

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Additional identifiers

Protocol serial number
V1.0

Study information

Scientific Title
Translating research into clinical and community practice: a multi-centre statistical and economical modelling of risk-based stratified and personalised screening for complications of diabetes in India (SMART India).

Acronym
SMART India

Study objectives
We hypothesise that non-laboratory tests may be sufficient to identify pre-diabetic and diabetic patients. We also hypothesise that patients with complications of diabetes can be discriminated from persons with no complications by one or a combination of tests that may be more cost-effective than current standard tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Vision Research Foundation, Institutional Review Board 09/05/2018, reference: 674A-2018-P

Primary study design
Observational

Study design
Observational cross-sectional study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diabetes

Interventions
Trialists will identify 3 separate clusters of urban, rural and a special population per 20 regions in India. They will visit 2000 consecutive homes in each cluster to invite the adult family members to participate in this study. After written informed consent, the trialists will obtain demographic data, and ask participants to complete questionnaires. They will also obtain blood pressure and blood sugar measurements from participants. Patients with diabetes or with a blood test positive for diabetes based on standard tests will complete further questionnaires (EuroQol-5D (EQ-5D) andVision and Quality of Life Index (VisQOL)) and expenses data, and have blood lipid tests and urine test for microalbuminuria. Retinal photography will also be completed. The retinal images will be sent for grading by primary and secondary graders, and an arbitration grader if required. The accuracy of non-laboratory tests will be measured against standard diagnostic tests for diabetes. Furthermore, accuracy of non-laboratory tests will be measured against standard tests for complications of diabetes.

Intervention Type
Not Specified

Primary outcome(s)
Diagnostic accuracy and sensitivity of non-laboratory versus laboratory tests to diagnose pre-diabetes and diabetes, assessed at the study visit by the proportion of people who test positive for diabetes (true positive rate) and the proportion of test negatives who are true negatives (negative predictive value). The accuracy of non-laboratory tests will be defined by the results of standard diabetes diagnostic tests.

Key secondary outcome(s)
The following are assessed at the study visit:
1. Specificity (true negative rate):
1.1. The proportion of people who do not have diabetes who test negative in blood tests
1.2. The proportion of people who do not have microalbuminuria who test negative in urine tests
1.3. The proportion of people who do not have diabetic retinopathy who test negative in retinal imaging
1.4. The proportion of people who do not have increased blood pressure and/or blood lipids who test negative in blood tests
1.5. The proportion of people who do not have more than one complication of diabetes who test negative in blood tests
2. Sensitivity (true positive rate):

2.1. Microalbuminuria:
2.1.1. The proportion of people who test positive for microalbuminuria
2.1.2. Accuracy of the non-laboratory test (index test) will be defined by the results of the standard panel of diagnostic tests for microalbuminuria
2.2. Diabetic retinopathy:
2.2.1. The proportion of people who test positive for diabetic retinopathy
2.2.2. Accuracy of the non-laboratory test (index test) will be defined by the results of the standard panel of diagnostic tests for diabetic retinopathy and complications of diabetes
2.3. Blood pressure and/or blood lipids:
2.3.1. The proportion of people who test positive for increased blood pressure and/or blood lipids
2.3.2. Accuracy of the non-laboratory test (index test) will be defined by the results of the standard panel of diagnostic tests for macrovascular complications of diabetes
3. Cost-effectiveness of non-laboratory tests or alternate tests compare to standard blood tests for diabetes diagnosis
4. Test acceptability, assessed using a short questionnaire comparing the acceptability of non-laboratory tests with standard diagnostic tests
5. Overall and regional prevalence of diabetic retinopathy and sight-threatening retinopathy, assessed by examining adjusted prevalence of diabetic retinopathy at national, regional and community worries
6. Qualitative evaluation of enhancers of the diabetes care pathway, assessed using Medical Research Council (MRC) guidance on process evaluations (including intervention, context, implementation, mechanisms of impact and outcomes). These components will be studied using quantitative and qualitative methods including questionnaires, on-site visits and interviews.

Completion date
12/09/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Able to give informed consent

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment

42416

Key exclusion criteria
1. Vulnerable adults in whom it may not be possible to carry out all tests
2. Anyone in the opinion of the health worker deemed not appropriate to be screened

Date of first enrolment
25/08/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
India

Study participating centre
Sankara Nethralaya - Chennai
Sankara Nethralaya (Main Campus)
No. 41 (old 18), College Road,
Chennai
India
600 006

Study participating centre
Dr. Mohan's Diabetes Specialities Centre - Chennai
No.6-B, Conron Smith Road,
Near Satyam Cinemas, Gopalapuram,
Chennai
India
600086.

Study participating centre
Aravind Eye Hospital - Madurai
1, Anna Nagar Main Road, Near Star Residency Hotel, Sathamangalam
Madurai
India
625020

Study participating centre
LVP Eye Institute - Hyderabad
Kallam Anji Reddy Campus, L V Prasad Marg, Banjara Hills, Opp. PVR

Hyderabad
India
500034

Study participating centre
Sankara Nethralaya - Kolkata
No. 147, E M Bypass, Mukundapur Market, Satyajit Kanan, Mukundapur
Kolkata
India
700099

Study participating centre
Dr. Mohan's Diabetes Specialities Centre - Bangalore
No. 1, HAL Second “A” Stage, Near Domlur Flyover, 100 Feet Road, Indiranagar
Bengaluru
India
560008

Study participating centre
Aravind Eye Hospital - Coimbatore
CBE City Centre Cowly Brown Road, R.S. Puram
Coimbatore
India
641002

Study participating centre
Giridhar Eye Institute - Cochin
SSM EYE RESEARCH FOUNDATION, C/o. Giridhar Eye Institute, 28/2576-A,, Ponneth Temple Road, Near Ponneth Temple, Kadavanthra
Kochi
India
682020

Study participating centre
Aditya Jyot Foundation for Twinkling Little Eyes - Mumbai
Plot No. 153, Road No. 9, Major Parmeshwaran Road, Opp S.I.W.S. College Gate No. 3, Wadala
Mumbai
India
400031

Study participating centre
Dr Tony Fernandez Eye Hospital - Aluva
High Road, Opp.Govt Boys Higher Secondary School
Aluva
India
683101

Study participating centre
Shroff Charitable Hospital - New Delhi
5027, Kedarnath Road, Beside Vani Prakashan, Daryaganj
New Delhi
India
110002

Study participating centre
LVP Eye Institute - Bhubaneshwar
Mithu Tulsi Chanrai Campus, Patia Road
Bhubaneswar
India
751024

Study participating centre
Sankaradev Nethralaya - Gauhati
96, Basistha Road, Beltola
Guwahati
India
781028

Study participating centre
Vision Academy - The Socio Medical Society - Bhopal
E-7/378, Link Rd Number 3, Opp. Hanuman Mandir, 1100 Quarters, Arera Colony
Bhopal
India
462016

Study participating centre
Sri Sadguru Nethra Chikatsalaya - Chitrakoot
Janki Kund

Chitrakoot
India
485334

Study participating centre
Aravind Nethralaya - Raipur
Shri Aurobindo Nethralaya, Near M.M.I. Hospital, 02, Dhamtari Rd, Pachpedi Naka, Chhatisgarh
Raipur
India
492001

Study participating centre
MA Netra Niramay Niketan - Haldia
Viveknagar, P.O. Chaitanyapur (Haldia), Dist. Purba Medinipur, Purba Medinipur
Haldia
India
721645

Study participating centre
Little Flower Hospital & Research Center - Angamaly
Department of Ophthalmology,
Little Flower Hospital and Research Centre,
P.O. Box NO. 23
Angamaly
India
683572

Study participating centre
Ganapathy Nethralaya - Jalna
Shri Ganapati Netralaya,
Devalgaon Raja-Mantha road,
Opposite Janta High school
Janla
India
431203

Study participating centre
HV Desai Hospital - Pune
PBMA's H. V. Desai Eye Hospital,
Survey No. 93, Taravade Vasti,
Mohammedwadi Road, Hadapsar

Pune
India
411060

Sponsor information

Organisation
Vision Research Foundation

Funder(s)

Funder type
Not defined

Funder Name
Global Challenge Research Fund, Medical Research Council, UK

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
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/10/2022	07/12/2022	Yes	No
Protocol article		12/12/2020	10/08/2021	Yes	No