

The Kilimanjaro Diabetic Programme: the development of a sustainable regional eye health screening program to prevent blindness among diabetic patients due to diabetic retinopathy

Submission date 23/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/06/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/05/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial of screening strategies for diabetic retinopathy in Kilimanjaro region: a randomised controlled trial of the effect of a screening camera on uptake of screening for diabetic retinopathy (phase I) and a randomised controlled trial of the effect of mobile telephone text reminders of screening appointments on uptake of screening for diabetic retinopathy (phase II)

Study objectives

Diabetes is a growing problem in Sub Saharan Africa. The number of diabetics in Eastern Africa is expected to reach 1.4 million by 2025. A high proportion of these patients develop sight threatening diabetic retinopathy. Uptake of screening for retinopathy is very poor throughout the region. We hypothesise that taking screening to the patients in diabetic clinics rather than asking them to go to an eye clinic and telephoning them prior to the screening appointment will lead to improvements in the uptake of screening.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Tumaini University (Tanzania) Ethics Committee approved in January 2009 (ref: 241)

Study design

Single centre randomised interventional screening trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Diabetes mellitus, diabetic retinopathy

Interventions

Phase I:

1. Intervention group: A digital diabetic retinopathy screening camera will be placed in the diabetic clinic at KCMC
2. Control group: patients will be advised to go to the eye clinic at KCMC for a dilated screening examination by an ophthalmologist
3. All patients will receive 3 information leaflets on diabetic retinopathy and be counselled by the health workers in the diabetic clinic that they should have screening for diabetic retinopathy
4. Visual acuity measurement will be performed and dilating drops installed by the screening team

Phase II:

1. The retinopathy screening camera will go to all district diabetic clinics twice in the 6 month intervention period
2. Patients registered at these clinics will all be advised by clinic staff to attend for retinopathy screening
3. The intervention group will receive a text message by mobile phone advising them of the date of the screening and inviting them to come

Intervention Type

Other

Phase

Phase I/II

Primary outcome measure

Uptake of screening for diabetic retinopathy, measured in August 2011

Secondary outcome measures

Measured in January 2012:

1. Prevalence of diabetic retinopathy in urban and rural diabetic patients in Kilimanjaro region
2. Prevalence of cataract in urban and rural diabetic patients in Kilimanjaro region

Overall study start date

10/12/2010

Completion date

31/07/2011

Eligibility

Key inclusion criteria

All known adult diabetic patients resident in Kilimanjaro region and attending a diabetic clinic at Kilimanjaro Christain Medical Centre (KCMC) or at one of the district diabetic clinics in the 6 rural districts of Kilimanjaro region

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Phase 1: 250; phase II: 500

Key exclusion criteria

1. Diabetic patients from outside Kilimanjaro region attending the above clinics
2. Refusal or withdrawal of consent
3. Psychiatric illness preventing screening examination
4. Patients too ill on the day of screening to have an eye examination

Date of first enrolment

10/12/2010

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

Tanzania

Study participating centre

Eye Department

Moshi

Tanzania

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Sponsor information

Organisation

Christoffel Blinden Mission (CBM) e.V. (Germany)

Sponsor details

Nibelungenstrasse 124

Bensheim

Germany

D-64625

Sponsor type

Charity

Website

<http://www.cbm.de>

ROR

<https://ror.org/04bc8dn02>

Funder(s)

Funder type

Charity

Funder Name

Christoffel Blinden Mission (CBM) e.V. (Germany)

Funder Name

AusAid (Australia)

Alternative Name(s)

AusAID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	comic strip development	19/05/2022	23/05/2022	Yes	No
Other publications	screening programme development	19/05/2022	23/05/2022	Yes	No