

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

<b>Submission date</b> 23/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/05/2022	<b>Condition category</b> 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

### Contact name

Dr Anthony Hall

### Contact details

Eye Department  
Kilimanjaro Christian Medical Centre  
PO Box 3010  
Moshi  
Tanzania

No telephone contact available  
[abhall@kcco.net](mailto:abhall@kcco.net)

## 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?
<a href="#">Other publications</a>	comic strip development	19/05/2022	23/05/2022	Yes	No
<a href="#">Other publications</a>	screening programme development	19/05/2022	23/05/2022	Yes	No