

# Gastric cancer in Zambian adults

<b>Submission date</b> 26/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/07/2013	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Gastric cancer is a common cause of cancer death in Zambia as elsewhere. There are no interventions (treatment) available for prevention which can be applied to an African population. We have observed that over the last 30 years there appears to have been a trend towards diagnosis at a younger age. This study is designed to test the hypothesis that HIV and /or dietary factors (particularly antioxidant intake in the form of fruit and vegetables) might contribute to what appears to be a changing epidemiology.

### Who can participate?

Patients presenting to the endoscopy unit of the University Teaching Hospital, Lusaka, Zambia.

### What does the study involve?

Participants were recruited at the time of endoscopy which has been requested by their physician. If a lesion was seen which is suspicious for gastric cancer, they were recruited if the tests confirmed the diagnosis of gastric cancer. Controls were recruited from patients seen subsequently who have normal endoscopy and are the same sex and in the same age band.

### What are the possible benefits and risks of participating?

The benefits to the individual are minimal except for the additional attention they will receive. The risks are only the inconvenience of answering the questions and submitting blood and urine samples.

### Where is the study run from?

The University Teaching Hospital, Lusaka, Zambia.

### When is the study starting and how long is it expected to run for?

The study started in December 2010 and completed in January 2012.

### Who is funding the study?

National Institutes of Health, USA.

### Who is the main contact?

Dr Paul Kelly  
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# Contact information

**Type(s)**

Scientific

**Contact name**

Dr Paul Kelly

**Contact details**

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# Additional identifiers

**Protocol serial number**

TROPGAN0005

# Study information

**Scientific Title**

Gastric cancer in Zambian adults: a case-control study

**Study objectives**

That gastric cancer epidemiology in Zambia is changing due to the emergence of Human immunodeficiency virus (HIV) and/or adverse dietary factors.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University of Zambia Biomedical Research Ethics Committee, 15/04/2010, reference number 008-02-10

**Study design**

Case-control study

**Primary study design**

Observational

**Study type(s)**

Screening

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

## Gastric adenocarcinoma

### Interventions

No interventions are planned. The study is designed to assess HIV, socio-demographic and behavioural risk factors, dietary intakes, and urine isoprostane excretion. Socio-demographic and behavioural (smoking, alcohol use) factors are assessed by interview using a standard questionnaire at the time of enrolment. Blood samples are tested for HIV using Unigold and Determine rapid tests. Urine isoprostane excretion is assessed using Enzyme-linked immunosorbent assay (ELISA) and (in a subset) High-performance liquid chromatography (HPLC).

The study is a case-control study so all assessments are immediate or retrospective and no formal follow-up is planned. All patients are referred appropriately in the light of their pathology results.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome(s)

1. HIV status
2. Smoking and alcohol intake
3. Dietary intake assessed by food frequency questionnaire
4. Antioxidant status assessed by urinary isoprostane excretion

### Key secondary outcome(s)

Other socio-demographic risk factors

1. Age
2. Sex
3. Wealth (measured on an asset scale)
4. Smoking
5. Alcohol use

### Completion date

31/01/2012

## Eligibility

### Key inclusion criteria

Cases: Histologically confirmed cases of gastric adenocarcinoma presenting to the endoscopy unit of the University Teaching Hospital (UTH), Lusaka, Zambia.

Controls:

1. Patients presenting to UTH endoscopy unit with no macroscopic abnormality on endoscopy
2. Age- and sex- matched to cases in a ratio of 2:1

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Patients already receiving chemo- or radio- therapy

**Date of first enrolment**

01/12/2010

**Date of final enrolment**

31/01/2012

## Locations

**Countries of recruitment**

United Kingdom

England

Zambia

**Study participating centre**

Blizard Institute

London

United Kingdom

E1 2AD

## Sponsor information

**Organisation**

Queen Mary, University of London (UK)

**ROR**

<https://ror.org/026zzn846>

## Funder(s)

Funder type

Government

Funder Name

National Institutes of Health (NIH) (USA) grant ref: R24TW007988

Funder Name

American Relief and Recovery Act (USA)

Results and Publications

Individual participant data (IPD) sharing plan

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="#">Results article</a>	results	01/05/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes