

# 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  
m.p.kelly@qmul.ac.uk

# Contact information

## Type(s)

Scientific

## Contact name

Dr Paul Kelly

## Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TROPAN0005

# 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

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**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**

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 measure**

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

**Secondary outcome measures**

Other socio-demographic risk factors

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

**Overall study start date**

01/12/2010

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

180

**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**

England

United Kingdom

Zambia

**Study participating centre**

Blizard Institute

London

United Kingdom  
E1 2AD

## Sponsor information

### Organisation

Queen Mary, University of London (UK)

### Sponsor details

c/o Paul Kelly  
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### Sponsor type

University/education

### Website

<http://www.smd.qmul.ac.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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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