

Gastric cancer in Zambian adults

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

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

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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?
Results article	results	01/05/2013		Yes	No