Double blind, placebo-controlled, randomised clinical trial to evaluate the efficacy of cotrimoxazole given as prophylaxis in reducing mortality in human immunodeficiency virusinfected adults with tuberculosis

Recruitment status No longer recruiting	Prospectively registered	
	☐ Protocol	
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category	Individual participant data	
	No longer recruiting Overall study status Completed	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LUCOT GMP1

Study information

Scientific Title

Acronym

LUCOT

Study objectives

Co-trimoxazole given as daily prophylaxis will reduce mortality in human immunodeficiency virus (HIV)-infected adults with tuberculosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the University of Zambia Research Ethics Committee and the University College London and UCL Hospitals NHS Joint Committee on Research Ethics

Study design

Double-blind, placebo-controlled, randomised clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Tuberculosis and HIV/AIDS

Interventions

Patients are randomised to receive 960 mg co-trimoxazole daily versus placebo.

Intervention Type

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Co-trimoxazole

Primary outcome measure

- 1. All cause mortality
- 2. Adverse events leading to interruption of trial drug

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2000

Completion date

01/09/2004

Eligibility

Key inclusion criteria

- 1. Adults greater than 16 years old
- 2. HIV-infected
- 3. Newly diagnosed pulmonary tuberculosis
- 4. Had a permanent residential address
- 5. Not pregnant
- 6. Willing to give informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1045

Key exclusion criteria

- 1. Pregnant
- 2. Terminally ill World Health Organization (WHO) stage 4 patients
- 3. History of sulfonamide allergy
- 4. Already receiving co-trimoxazole

Date of first enrolment

01/06/2000

Date of final enrolment 01/09/2004

Locations

Countries of recruitment

England

United Kingdom

Zambia

Study participating centre University College London London United Kingdom W1T 4JF

Sponsor information

Organisation

University College London (UK)

Sponsor details

46 Cleveland Street London England United Kingdom W1T 4JF +44 (0)207 67991887 rebmfar@ucl.ac.uk

Sponsor type

University/education

Website

http://www.ucl.ac.uk/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

Department for International Development (DFID) (UK) - Health and Population Division (HPD)

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	10/07/2008		Yes	No