

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

Submission date

13/04/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

11/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/07/2008

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Co-trimoxazole

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Zambia

Study participating centre

University College London
London
United Kingdom
W1T 4JF

Sponsor information

Organisation

University College London (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

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