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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

Registration date
11/05/2006

Last Edited
18/07/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Drug

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
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Sponsor information

Organisation
University College London (UK)

Sponsor details
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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