ISRCTN15281875 https://doi.org/10.1186/ISRCTN15281875

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

Contact name
Prof Alimuddin Zumla

Contact details
University College London
Centre for Infectious Diseases and International Health
Windeyer Institute of Medical Sciences
46 Cleveland Street
London
United Kingdom
W1T 4JF
+44 (0)207 6799311
a.zumla@ucl.ac.uk

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

Primary study design
Interventional

Study design
Double-blind, placebo-controlled, randomised clinical trial

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