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Primary prevention of invasive cryptococcal disease using fluconazole prophylaxis in Human Immunodeficiency Virus (HIV) infected Ugandans

Submission date	Recruitment status	[X] Prospectively registered
18/05/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/05/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2017	Infections and Infestations	

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
G0100035

Study information

Scientific Title
Primary prevention of invasive cryptococcal disease using fluconazole prophylaxis in Human Immunodeficiency Virus (HIV) infected Ugandans

Acronym
CRYPTOPRO-UGANDA

Study objectives
Designed to determine whether routine use of fluconazole primary prophylaxis in HIV-infected African patients with relatively advanced HIV disease reduces the incidence of and mortality from invasive cryptococcal disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
HIV, Acquired Immunodeficiency Syndrome (AIDS)

Interventions
The trial will take place in TASO Masaka in collaboration with the MRC Programme on AIDS in Uganda and will last for 3.5 years in total. A cohort of 590 non-pregnant adults will be randomised 1:1 to placebo or fluconazole over 18 months. Fluconazole 200 mg three times a week will be compared to placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluconazole

Primary outcome measure
Invasive cryptococcal disease and mortality attributable to cryptococcal disease

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2003

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Adults (age >15)
2. CD4 count below 200 cells
3. Giving informed consent to the study

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
590

Key exclusion criteria
1. Pregnancy
2. Previous cryptococcal disease
3. Symptoms/signs suggestive of cryptococcal disease or a positive serum cryptococcal antigen test
4. Moribund or bedbound patients who are terminally ill
5. Current antiretroviral therapy

Date of first enrolment

01/10/2003

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

Uganda

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine
Liverpool
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/12/2011		Yes	No
Results article	results	13/07/2017		Yes	No