

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

Submission date 18/05/2001	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 18/05/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/07/2017	Condition category Infections and Infestations	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Invasive cryptococcal disease and mortality attributable to cryptococcal disease

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Uganda

Study participating centre

Liverpool School of Tropical Medicine

Liverpool

United Kingdom
L3 5QA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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

