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Short course interferon-gamma for human immunodeficiency virus (HIV)-associated cryptococcal meningitis

Submission date	Recruitment status	[_] Prospectively registered
20/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/08/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2015	Infections and Infestations	[_] Record updated in last year

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
CM-IFN.1

Study information

Scientific Title
Randomised controlled trial of short course adjunctive interferon gamma for inital treatment of human immunodeficiency virus (HIV)-associated cryptococcal meningitis: effect on rate of clearance of infection and immune response

Study objectives
Short course adjunctive interferon gamma will increase rate of sterilisation of cerebrospinal fluid (CSF) in human immunodeficiency virus (HIV)-associated cryptococcal meningitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: London Surrey Borders Research Ethics Committee (REC), 23/05/2007
2. South Africa: University Cape Town REC, 25/06/2007

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cryptococcal meningitis

Interventions
Group 1: Amphotericin B 1 mg/kg/d plus flucytosine 25 mg/kg four times a day (qds) for two weeks.
Group 2: Amphotericin B 1 mg/kg/d plus flucytosine 25 mg/kg qds for two weeks plus interferon (IFN)-gamma, 100 micrograms subcutaneous (s/c) three times a week for two weeks (six doses).
Group 3: Amphotericin B 1 mg/kg/d plus flucytosine 25 mg/kg qds for two weeks plus IFN-gamma, 100 micrograms s/c three times a week on days 1 and 3 (two doses).

In all steps, after two weeks, all patients will receive fluconazole 400 mg/d for eight weeks, followed by fluconazole 200mg/d thereafter.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Interferon gamma

Primary outcome measure
Early Fungicidal Activity (EFA, the rate of sterilisation of CSF), for each treatment arm.

Secondary outcome measures
1. The proportions of patients in each arm suffering clinical and laboratory-defined side effects
2. Mortality at 2 and 10 weeks by treatment group

Overall study start date
10/07/2007

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Patients greater than 18 years (either sex) with a first episode of cryptococcal meningitis on basis of CSF India ink or CSF cryptococcal antigen.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 (40 per arm, three arms)

Key exclusion criteria
1. Alanine Aminotransferase (ALT) greater than five times upper limit of normal
2. Polymorphonuclear leukocytes (PMNs) less than 500 x 10^6/L
3. Platelets (Plts) less than 50,000 x 10^6/L
4. Pregnancy or lactation

5. Previous serious reaction to study drugs
6. Concomitant medication that is contraindicated with any study drugs
7. Already on Anti-Retroviral Therapy (ART)

Date of first enrolment
10/07/2007

Date of final enrolment
10/07/2009

Locations

Countries of recruitment
South Africa

United Kingdom

Study participating centre
St George's University of London
London
United Kingdom
SW17 ORE

Sponsor information

Organisation
St George's University of London (UK)

Sponsor details
Research Office
Cranmer Terrace
London
United Kingdom
SW17 ORE

Sponsor type
University/education

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

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

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