

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

Submission date 20/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/02/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 initial 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 $500 \times 10^6/L$
3. Platelets (Plts) less than $50,000 \times 10^6/L$
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