ISRCTN77861053 https://doi.org/10.1186/ISRCTN77861053

An evaluation of the impact of early initiation of Highly Active Anti-Retroviral Therapy (HAART) on Tuberculosis (TB) treatment outcomes for TB patients co-infected with Human Immunodeficiency Virus (HIV)

Submission date 29/03/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/03/2006	**Overall study status** Completed	
Last Edited 30/09/2014	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Philip Onyebujoh

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 4478
onyebujohp@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
South Africa (A50560), Zambia (A50636), Uganda (A30224) and Tanzania (A30213)

Study information

Scientific Title

Acronym
TB-HAART

Study objectives
That early concomitant treatment with TB and HIV medications may improve TB outcomes and improve survival.

As of 12/07/2011 the anticipated end date for this trial has been updated from 30/05/2009 to 30 /06/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 17/08/2005.

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

Health condition(s) or problem(s) studied
Tuberculosis (TB) and Human Immunodeficiency Virus (HIV) co-infections

Interventions
Placebo controlled trial.

Patients with TB-HIV co-infection with CD4 counts above 220, to be randomised into combined treatment with anti-TB and HIV medications and then HAART after six months, or anti-TB plus placebo for six months and then HAART thereafter.

All patients will be on HAART after six months, and post-trial medication is provided by the governments of participating countries.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Highly Active Anti-Retroviral Therapy (HAART)

Primary outcome measure
The proportion of subjects reaching the composite endpoint of treatment failure or death at six months after the initiation of short-course chemotherapy for TB.

Secondary outcome measures
1. The proportion of patients with TB relapse in the 24 months after initiation of short course chemotherapy in the two treatment groups
2. The proportion of patients reaching the multiple endpoint of treatment failure, relapse or death evaluated at 24 months after TB treatment initiation
3. The safety and tolerability of HAART used concomitantly with anti-TB medication

Overall study start date
30/05/2006

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. HIV treatment naive patients (established by history)
3. CD 4 T-cell count between 220-500 cells/l
4. No history of previous anti-TB chemotherapy
5. A traceable home address and contact details to facilitate home visits with a firm commitment to remain traceable and to be able to access a defined treatment/service point for 24 months
6. Not enrolled in any other drug or treatment trials
7. Informed consent for HIV testing (since the study population will be smear positive TB patients co-infected with HIV)
8. Informed consent to participate in the trial
9. For female subjects, the following conditions are to be met:
9.1. Has been post-menopausal for at least one year, or
9.2. Is surgically incapable of bearing children, or
9.3. Is of childbearing potential and all of the following conditions are met:

9.3.1. Had a normal menstrual flow within one month before study entry
9.3.2. Has a negative pregnancy test (urine) immediately before study entry (and later confirmed by serum pregnancy test)
9.3.3. Must agree to use an accepted method of contraception (i.e. barrier methods or intrauterine device [IUD]). The subject must agree to continue with the same method throughout the study
Note: If a patient is using a long-acting hormonal contraceptive (such as Depot-Provera), the patient can be enrolled in the study, however she should be advised to use it in conjunction with a barrier method or IUD due to the known pharmacokinetic interaction between the various study medications and hormonal contraceptives. If an oral hormonal agent is in use, the patient should be advised to change the method of contraception in favour of barrier methods.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1900

Key exclusion criteria
1. Evidence (laboratory and clinical history) of pre-existing non-tuberculosis disease likely to affect the response to, or assessment of treatment effects or represent contraindications to the study medication:
1.1. Diabetes mellitus
1.2. Liver impairment (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] greater than 2 x the upper limit of normal value)
1.3. Renal failure (serum creatinine greater than 2.0 mg/dl)
1.4. Epilepsy
1.5. Optical neuritis
1.6. Pancreatitis (lipase greater than 140 U/l)
1.7. Neutropenia (total neutrophil count less than 1200 cells/l)
1.8. Severe anaemia (haemoglobin less than 6.9 g/dl)
1.9. Any other condition that in the view of the country Principal Investigator represents a contraindication to the study medication
2. Mental illness (clinical suspicion of schizophrenia, manic-depressive illness, dementia)
3. Stage IV disease (according to World Health Organization [WHO] staging system)
4. Weight below 30 kg
5. Moribund or clinical evidence of severe illness

Date of first enrolment
30/05/2006

Date of final enrolment

30/06/2014

Locations

Countries of recruitment
South Africa

Switzerland

Tanzania

Uganda

Zambia

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

Sponsor details
20 Avenue Appia
Geneva 27
Switzerland
CH-1211
+41 (0)22 791 4478
onyebujohp@who.int

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Funder Name
US Agency for International Development (USAID) (USA)

Funder Name
GlaxoSmithKline (GSK) - drug supply

Funder Name
Merck & Co Inc. - drug supply

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	01/07/2014		Yes	No