# An evaluation of two eight-month regimens of chemotherapy for the treatment of newly diagnosed pulmonary tuberculosis

Submission date	Recruitment status	Prospectively registered
06/04/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/04/2010	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
15/04/2010	Infections and Infestations	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

Type(s)

Scientific

#### Contact name

**Prof Donald Enarson** 

#### Contact details

International Union Against Tuberculosis and Lung Disease Paris France 75006

## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

An evaluation of two eight-month regimens of chemotherapy for the treatment of newly diagnosed pulmonary tuberculosis: A multicentre, single-blinded, randomised controlled trial

#### Acronym

Study A

#### **Study objectives**

An 8-month regimen for the treatment of pulmonary tuberculosis with either a daily or three times weekly initial intensive phase is not inferior to a six month standard treatment regimen

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The study protocol was reviewed and approved by the Ethics Advisory Group of The International Union Against Tuberculosis and Lung Disease, approved on the 1st of December 2000 and one year thereafter

#### Study design

Multicentre randomised single-blind 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 contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Smear-positive pulmonary tuberculosis

#### **Interventions**

Participants from 8 sites with smear positive pulmonary tuberculosis who had never previously treated were randomly assigned from a table of random numbers to one of three treatment regimens:

- 1. Intensive Initial Treatment: 2 months of daily isoniazid, rifampicin, pyrazinamide and ethambutol followed by 6 months of daily isoniazid and ethambutol
- 2. Intermittant Initial Treatment: 2 months of thrice-weekly isoniazid, rifampicin, pyrazinamide

and ethambutol followed by 6 months of daily isoniazid and ethambutol

3. Standard Treatment: 2 months of daily isoniazid, rifampicin, pyrazinamide and ethambutol followed by 4 months of daily isoniazid and rfampicin

#### **Intervention Type**

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The proportion of patients with negative cultures at two months and the status of patients 12 months after completion of chemotherapy (i.e. at 18 or 20 months after start of chemotherapy depending on the regimen). The two-month culture result was chosen to compare the rate of sputum conversion of the three times weekly intensive phase with that of the daily intensive phase

#### Secondary outcome measures

The proportion of failures at the end of chemotherapy (at 6 or 8 months after start of chemotherapy) and the proportion patients with adverse events requiring stopping of their chemotherapy or an interruption of treatment for 7 days or more

#### Overall study start date

01/03/1998

#### Completion date

01/12/2001

# Eligibility

#### Key inclusion criteria

- 1. Age 15 to 65 years
- 2. Two sputum specimens positive for acid-fast bacilli on direct smear microscopy
- 3. No previous anti-tuberculosis chemotherapy for more than one month
- 4. A specific home address readily accessible for visiting in case of a failure to attend
- 5. Informed consent given and agreed to participate in the study and to give a sample of blood, urine or saliva for HIV testing

## Participant type(s)

Patient

## Age group

Adult

#### Sex

Both

## Target number of participants

1,500

#### Key exclusion criteria

- 1. So ill they were thought unlikely to survive the initial weeks of treatment
- 2. Presence of extra-pulmonary tuberculosis
- 3. Concomitant diseases likely to prejudice the response to, or assessment of, treatment such as
- 3.1. Diabetes
- 3.2. Liver disease
- 3.3. Nephritis
- 3.4. Blood disorders
- 3.5. Epilepsy
- 3.6. Peripheral neuritis
- 4. Known to be pregnant
- 5. Suffering from a psychiatric illness or alcoholism

#### Date of first enrolment

01/03/1998

#### Date of final enrolment

01/12/2001

## Locations

## Countries of recruitment

Benin

China

France

Guinea

Mozambique

Nepal

Tanzania

## Study participating centre

International Union Against Tuberculosis and Lung Disease

Paris

France

75006

# Sponsor information

#### Organisation

International Union Against Tuberculosis and Lung Disease (France)

#### Sponsor details

68 Boulevard Saint-Michel Paris France 75006

#### Sponsor type

Charity

#### Website

http://www.theunion.org

#### **ROR**

https://ror.org/037x4qk98

# Funder(s)

### Funder type

Other

#### **Funder Name**

Ministry of Foreign Affairs - Directorate of Development and Technical Cooperation (Ministère des Affaires Etrangères - Direction du Développement et de la Coopération Technique) (France)

#### **Funder Name**

The Norwegian Heart & Lung Association (Norway)

#### **Funder Name**

Norwegian Agency for Development Cooperation (NORAD) (Norway)

#### Funder Name

US Agency for International Development (USAID) (USA)

#### **Funder Name**

Trustees of the Royal Free Hospital (UK)

#### Funder Name

Kuratorium Tuberkulose in der Welt e.V (Germany)

#### **Funder Name**

Hoechst Marion Roussel S.p.A. (Italy)

#### Funder Name

Fatol Arzneimittel GmbH (Germany)

#### Funder Name

Bracco S.p.A. (Italy)

# **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	01/10/2004		Yes	No