

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

<b>Submission date</b> 06/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/04/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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  
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## Additional identifiers

## 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

### **Primary study design**

Interventional

### **Study design**

Multicentre randomised single-blind controlled trial

### **Study type(s)**

Treatment

### **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 rifampicin

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**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

### 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?
<a href="#">Results article</a>	results	01/10/2004		Yes	No