

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

Submission date 06/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/04/2010	Condition category 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

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Contact details

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Paris
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75006

Additional identifiers

Protocol serial number

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

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 rfampicin

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?
Results article	results	01/10/2004		Yes	No