ISRCTN19832141 https://doi.org/10.1186/ISRCTN19832141

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

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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