

# A randomised trial of risks/benefits of a policy of chemoprophylaxis with Human Immunodeficiency Virus (HIV) at risk of tuberculosis (TB-1)

<b>Submission date</b> 03/10/2000	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2000	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/07/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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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## Additional identifiers

### Protocol serial number

G9703020

## Study information

Scientific Title

**Acronym**

TB-1

**Study objectives**

To evaluate, in individuals with HIV infection at increased risk of developing tuberculosis (TB), whether a policy of six months chemoprophylaxis with isoniazid plus monitoring to detect active TB is more effective than monitoring alone

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Not Specified

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

HIV, Acquired Immunodeficiency Syndrome (AIDS)

**Interventions**

1. Chemoprophylaxis with isoniazid plus monitoring
2. Monitoring alone

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

pyridoxine, isoniazid

**Primary outcome(s)**

Primary endpoint - the development of TB requiring treatment whether:

1. Confirmed on culture
2. Presumptive, based on smear or histological results
3. Diagnosed clinically only (including response to treatment)

**Key secondary outcome(s)**

Secondary endpoints include:

1. All cause mortality

2. Compliance (pill counts, urine tests for isoniazid)
3. Progression to new (non-recurrent) AIDS events

**Completion date**

01/09/2001

**Reason abandoned (if study stopped)**

Recruitment issues and drug logistics problems

## Eligibility

**Key inclusion criteria**

1. HIV infection;
2. Aged 13 or more including women of child bearing age
3. Are considered at increased risk of developing TB
4. At any stage of HIV disease except with a past or current diagnosis of TB
5. Are considered likely to survive for more than 3 months
6. Able to comply and give informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Women in first trimester of pregnancy
2. Prior or current diagnosis of TB or treatment with an anti TB drugs
3. Signs or symptoms suggesting TB where TB has not been excluded by CXR and three negative sputum smears
4. Close contacts of known cases of pulmonary TB where the clinician feels that isoniazid prophylaxis is indicated
5. Pre-existing disease which contraindicates treatment with isoniazid (such as grade 2 or worse peripheral neuropathy, liver disease, renal disease or alcoholism) or ALT or AST above 3x local upper limit of normal (ULN) or alkaline phosphatase above 5x ULN

**Date of first enrolment**

01/05/1998

**Date of final enrolment**

01/09/2001

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

## Funder(s)

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration