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

Submission date
03/10/2000

Recruitment status
Stopped

Registration date
03/10/2000

Overall study status
Stopped

Last Edited
29/07/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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. Conformed 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