ISRCTN41241584 https://doi.org/10.1186/ISRCTN41241584

Rifampin versus isoniazid for the treatment of latent tuberculosis

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/06/2015	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
NCT00170209

Secondary identifying numbers

MCT-44154

Study information

Scientific Title
Randomised clinical trial of four months rifampin versus nine months INH for the treatment of latent Tuberculosis

Study objectives
1. To compare the rate of adverse events resulting in permanent discontinuation of study drug, with 4RIF or 9INH given as daily
2. To compare the rate of compliance/completion of the two arms
3. To compare costs, overall, and related to adverse events, of the two regimens

As of 25/02/2009 this record was updated to include an amendment to the overall trial end date; the initial overall trial end date at the time of registration was 30/09/2006.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the McGill University Health Centre (MUHC), Montreal Chest Institute, Montreal, QC, 18/04/2001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Latent tuberculosis (TB) Infection

Interventions
One arm will receive nine months of isoniazid (INH) - the current standard therapy for this condition. The other group will receive four months of daily self-administered rifampin - a currently recommended alternative.

Trial details received: 12/09/2005

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rifampin, isoniazid

Primary outcome measure
Major adverse events requiring permanent discontinuation of study drug

Secondary outcome measures
1. Minor side effects
2. Compliance
3. Costs of Therapy

Overall study start date
01/04/2001

Completion date
30/12/2007

Eligibility

Key inclusion criteria
1. Close or casual contact of an active case pulmonary Tuberculosis (TB)
2. Aged 18 years and older, either sex
3. Documented tuberculin conversion within five years
4. Human immunodeficiency virus (HIV) positive, or other immune suppressed condition (e.g. corticosteroid therapy)
5. Apical/upper lobe fibronodular disease (with area greater than 2 cm^2), or other radiographic abnormalities
6. Underweight, diabetes, renal failure, or other medical risk factors
7. Recent (less than two years) arrival from country/region with TB incidence greater than 100 /100,000

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

1260 (847 recruited as of 30/01/2007 - end of recruitment)

Key exclusion criteria
1. Low risk reactors
2. Patients who were contacts of known INH resistant case
3. Known HIV-infected individuals on triple anti-retroviral therapy
4. Women of child bearing age taking oral contraceptives
5. Patients on any other medication with clinically important drug interaction with INH or RIF

Date of first enrolment
01/04/2001

Date of final enrolment
30/01/2007

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Chest Institute
Montreal
Canada
H2X 2P4

Sponsor information

Organisation
The Research Institute of the McGill University Health Centre (Canada)

Sponsor details
1650 Cedar Avenue
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-
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Sponsor type
University/education

ROR
https://ror.org/04cpxjv19

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44154)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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	18/11/2008		Yes	No
Results article	results	01/07/2010		Yes	No