

# Rifampin versus isoniazid for the treatment of latent tuberculosis

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/06/2015	<b>Condition category</b> 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

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00170209

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

Major adverse events requiring permanent discontinuation of study drug

**Key secondary outcome(s)**

1. Minor side effects
2. Compliance
3. Costs of Therapy

**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<sup>2</sup>), 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

## 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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Canada

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	18/11/2008		Yes	No
<a href="#">Results article</a>	results	01/07/2010		Yes	No