

# Trial of the efficacy of a second dose of BCG vaccination against tuberculosis (Avaliação da eficácia da segunda dose da vacina BCG em escolares)

<b>Submission date</b> 17/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/03/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The BCG vaccine protects against tuberculosis, a serious infection which affects the lungs. It has also been found to protect against leprosy, an infectious skin and nerve disease. The aim of this study is to assess the effectiveness of a second dose of BCG vaccination against tuberculosis and leprosy.

### Who can participate?

Schoolchildren aged 7 to 14 years attending the participating state schools

### What does the study involve?

Participating schools are randomly allocated to one of two groups: the intervention group and the control group. Participants in the intervention group schools receive a second BCG vaccination. Participants in the control group schools do not receive the second BCG vaccination. The number of cases of tuberculosis and leprosy are recorded in the two groups.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

767 state schools in the cities of Salvador and Manaus in Brazil

### When is the study starting and how long is it expected to run for?

June 1996 to June 2016

### Who is funding the study?

1. The Department For International Development (DFID) (UK)
2. Ministry of Health (Brazil)

Who is the main contact?  
Prof. Mauricio Lima Barreto

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Mauricio Lima Barreto

**Contact details**  
Instituto de Saúde Coletiva  
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## Additional identifiers

**Protocol serial number**  
R6715

## Study information

**Scientific Title**  
Trial of the efficacy of a second dose of BCG vaccination against tuberculosis (Avaliação da eficácia da segunda dose da vacina BCG em escolares)

**Acronym**  
BCGREVAC

**Study objectives**  
To estimate the efficacy of a second dose of BCG vaccination against tuberculosis and leprosy.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
1. Ethical Committee of the University Hospital Professor Edgard Santos (HUPES) of the Federal University of Bahia, 07/10/1996  
2. National Committee for ethics in Research (Comitê Nacional de Etica em Pesquisa-CONEP), 30 /10/2003, judgement ref: 770/2003, submission ref: 250000.106515/2003-02

**Study design**  
Cluster randomised trial, with schools being the unit of randomisation. There was no concealment of allocation or intervention and no placebo was used.

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Tuberculosis and leprosy

**Interventions**

The intervention was a single intradermal injection with BCG vaccine produced in Brazil using the Moreaux (Rio de Janeiro) strain. This will be a revaccination as children have a high coverage of BCG at birth. The control group will receive no vaccination.

The trial was conducted in two sites, the cities of Salvador and Manaus, in Brazil. Seven hundred and sixty seven state schools were included in the trial. Children in both treatment groups were visited at school to confirm their identification details and their arms were examined for BCG scars. Ascertainment of cases was through the tuberculosis control programme. Cases notified were reviewed independently by two chest physicians, who classified cases into confirmed (microbiological confirmation), probable (would treat based on the information from the records), suspected (no information in the record suggested this was not tuberculosis) and not tuberculosis (excluded from the analysis), and into pulmonary and non-pulmonary forms. A third specialist reviewed those classified differently by the two chest physicians. The validation was blind to vaccination.

Cases were linked to the study population in the study database. Linkage was done blind to vaccination status, based on the name of the child, the name of the mother, the sex and date of birth of the child. All possible matches were reviewed by a member of the study team to assess its reliability. Most were unique matches, with complete concordance on all variables. Home visits to a sample of cases not linked to the database identified only two cases (out of 144 visited) that belonged to the database.

Active informed consent was not obtained. This was because both intervention (BCG revaccination) and absence of intervention were in routine practice in different settings in Brazil at the time, and therefore an "opt out" form of consent was deemed acceptable: parents of children in schools allocated to vaccination were given written information about the vaccine and the trial and offered the opportunity to withdraw their child from the trial.

**Intervention Type**

Biological/Vaccine

**Primary outcome(s)**

1. Case of tuberculosis
2. Case of leprosy

**Key secondary outcome(s)**

1. Tuberculosis by form
2. Leprosy by form

**Completion date**

01/06/2016

# Eligibility

## Key inclusion criteria

School children aged 7 to 14 years in state schools

## Participant type(s)

Other

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

7 years

## Upper age limit

14 years

## Sex

All

## Key exclusion criteria

1. Children with special needs
2. Children who received more than one BCG vaccination

## Date of first enrolment

01/06/1996

## Date of final enrolment

01/06/2016

# Locations

## Countries of recruitment

Brazil

## Study participating centre

Universidade Federal da Bahia

Salvador

Brazil

40.110-040

# Sponsor information

**Organisation**

Institute for Collective Health (Instituto de Saúde Coletiva) (Brazil)

**ROR**

<https://ror.org/03k3p7647>

**Funder(s)****Funder type**

Government

**Funder Name**

Department for International Development

**Alternative Name(s)**

Department for International Development, UK, DFID

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Ministry of Health (Brazil)

**Results and Publications****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?
<a href="#">Results article</a>	results	01/11/2001		Yes	No
	results				

<a href="#">Results article</a>		01/04/2003	Yes	No
<a href="#">Results article</a>	results	01/04/2003	Yes	No
<a href="#">Results article</a>	results	01/12/2004	Yes	No
<a href="#">Results article</a>	results	01/10/2005	Yes	No
<a href="#">Results article</a>	results	08/10/2005	Yes	No
<a href="#">Results article</a>	results	24/06/2014	Yes	No
<a href="#">Protocol article</a>	protocol	01/10/2002	Yes	No
<a href="#">Protocol article</a>	protocol	01/03/2004	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No
				Yes