

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

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

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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?
Results article	results	01/11/2001		Yes	No
	results				

Results article		01/04/2003	Yes	No
Results article	results	01/04/2003	Yes	No
Results article	results	01/12/2004	Yes	No
Results article	results	01/10/2005	Yes	No
Results article	results	08/10/2005	Yes	No
Results article	results	24/06/2014	Yes	No
Protocol article	protocol	01/10/2002	Yes	No
Protocol article	protocol	01/03/2004	Yes	No